

FIXING THE FLAWS IN THE FEDERAL VACCINE INJURY COMPENSATION PROGRAM

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INTRODUCTION

Hannah Bruesewitz was born on October 20, 1991. Her pediatrician administered doses of the [diphtheria, pertussis, and tetanus (DTP)] vaccine according to the Center for Disease Control's recommended childhood immunization schedule. Within 24 hours of her April 1992 vaccination, Hannah started to experience seizures. She suffered over 100 seizures during the next month, and her doctors eventually diagnosed her with "residual

seizure disorder” and “developmental delay.” Hannah, now a teenager, is still diagnosed with both conditions.¹

In 1995, Hannah Bruesewitz’s parents embarked on an unsuccessful fifteen-year odyssey through the courts. Claiming that Hannah suffered vaccine-related injuries for which she was entitled to compensation, her parents litigated her case in every available forum, culminating in their recent loss in the U.S. Supreme Court.² Hannah’s parents first sought compensation, as they were required to do, under the National Childhood Vaccine Injury Act (Vaccine Act),³ a pioneering no-fault federal tort reform law that took effect two decades ago. The statute, preempting state product liability laws, mandates that all claims for compensation for injuries caused by the vaccines routinely given in the United States must first be brought and litigated in the U.S. Court of Federal Claims, with the Secretary of Health and Human Services (HHS) as the respondent.⁴ After exhausting this remedy, petitioners have the option of filing a civil action in state or federal court, on grounds not foreclosed by the Vaccine Act, against the manufacturer of the vaccine or the healthcare provider who administered it.⁵

After the Court of Federal Claims rejected Hannah’s parents’ petition for compensation, her parents filed a civil tort suit against the vaccine’s manufacturer.⁶ The complaint was dismissed in large part by the District Court, which held that the Vaccine Act’s preemption clause forbids a claim against a vaccine manufacturer based upon a design defect, which was Hannah’s parents’ most promising remaining ground for relief.⁷ On February 22, 2011, the U.S. Supreme Court affirmed the dismissal.⁸

Hannah’s case highlights a number of problems with the National Vaccine Injury Compensation Program (Vaccine Program or Vaccine Compensation Program)⁹ today. The program represented a legislative compromise involving the major interest groups working in the vaccine area, including vaccine manufacturers, physicians’ groups, healthcare providers, federal health agencies, and parent groups advocating on behalf

1. *Bruesewitz v. Wyeth L.L.C.*, 131 S. Ct. 1068, 1074–75 (2011) (footnotes omitted).

2. *Id.* at 1082.

3. National Childhood Vaccine Injury Act (Vaccine Act) of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2006)).

4. 42 U.S.C. § 300aa-11(a)(1) to (4) (2006).

5. *Id.* § 300aa-21(a).

6. *Bruesewitz*, 131 S. Ct. at 1075.

7. *Id.*

8. *Id.* at 1082.

9. 42 U.S.C. § 300aa-10.

of injured children.¹⁰ Now that the Vaccine Program has been operating for more than twenty years, we can reach several broad conclusions about its successes and failures in satisfying the objectives of these groups and the objectives of the legislation. First, it appears that the Program has been largely successful in providing excellent liability protection for the pharmaceutical industry that makes vaccines, as well as for the doctors and other healthcare providers who administer them. These groups have been extremely concerned about possible tort liability for alleged vaccine-related injuries.¹¹ While the Vaccine Act has not entirely eliminated all potential tort liability for manufacturers and healthcare providers, it has significantly minimized such liability, particularly after *Bruesewitz v. Wyeth*.¹² The interests of the federal health agencies involved in the vaccine area, including HHS, the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and several other agencies, have also been largely satisfied by ensuring a relatively constant supply of vaccines to the public and ensuring that a high number of Americans receive inoculations.¹³ However, the objectives of parents' groups and other advocates for children and adults who have suffered serious injuries after receiving vaccines have not been satisfied. For persons who may have been injured by vaccinations, the need for expeditious, generous, and predictable compensation remains unmet. Moreover, the process of adjudicating vaccine cases today is seriously flawed and in need of repair.

In this Article, I will examine the process of litigating vaccine injury claims in the Vaccine Compensation Program. The adjudicative process has changed over time, such that the program has become much different today than it was when the law was first enacted. The Vaccine Compensation Program is also very different from the program that the

10. Denis J. Hauply & Mary Mason, *The National Childhood Vaccine Injury Act: The Federal No-Fault Compensation Program that Gives a Booster for Tort Reform*, 37 FED. B. NEWS & J. 452, 452 (1990); Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 711–12 (2007).

11. Prior to the passage of the Vaccine Act, the persistent threat of tort liability claims caused pharmaceutical companies to consider and threaten to abandon the vaccine market, and some had already done so. There was real concern that there might be no manufacturers for certain vaccines in the United States. H.R. REP. NO. 99-908, pt. 1, at 6–7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347–48.

12. 131 S. Ct. 1068 (2011).

13. See Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 HEALTH AFF. 599, 599–60 (2005) (highlighting the correlation between record highs of immunization levels among young children and the reduction of disease incidence); cf. Rutkow et al., *supra* note 10, at 717–18 (describing the program as a “moderate success” that has “succeeded in reducing the number of lawsuits brought under the tort system”).

Supreme Court described in *Bruesewitz*. In the *Bruesewitz* opinion, the Supreme Court characterized the underlying proceedings before the special masters as involving “informal adjudication” which moves quickly to final resolution within 240 days of filing “except for two limited exceptions.”¹⁴ The Court added: “Fast, informal adjudication is made possible by the Act’s Vaccine Injury Table”¹⁵

These descriptions of the Vaccine Program would have been largely accurate when the Act was initially passed, but they are substantially inaccurate in describing how the program actually operates today. The adjudications today are typically not informal at all, virtually no cases are concluded within the 240-day deadline, and the Vaccine Injury Table,¹⁶ which was originally a central feature of the Vaccine Act and a key innovative provision of the Act, has been significantly changed and narrowed over the years so that today it plays only a limited role in Vaccine Act cases.¹⁷

The Vaccine Injury Table lists the specific injuries that the court recognizes as presumptively caused by a vaccine and the specified time limit for the occurrence of the onset of each listed injury.¹⁸ When the Vaccine

14. *Bruesewitz*, 131 S. Ct. at 1073.

15. *Id.*

16. 42 U.S.C. § 300aa-14(a) (2006).

17. See *infra* notes 72–74 and accompanying text; see also Stevens v. Sec’y of the Dep’t of Health & Human Servs., No. 99–594V, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001) abrogated in part by Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1281 (Fed. Cir. 2005).

18. The Vaccine Injury Table lists Table injuries as follows (partial list of vaccines):

Vaccine	Adverse Event	Time Interval
Measles, mumps and rubella virus-containing vaccine in any combination (e.g., MMR, MR, M, R)	Anaphylaxis or anaphylactic shock Encephalopathy (or encephalitis) Any acute complication or sequela (including death) of the above events	0–4 hours 5–15 days Not applicable
Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DT, Td, TT)	Anaphylaxis or anaphylactic shock Brachial neuritis Any acute complication or sequela (including death) of above events	0–4 hours 2–28 days Not applicable
Varicella vaccine	No condition specified for compensation	Not applicable
Rotavirus vaccine	No condition specified for compensation	Not applicable
Pneumococcal conjugate vaccines	No condition specified for compensation	Not applicable

HEALTH RES. & SERVS. ADMIN., NATIONAL CHILDHOOD VACCINE INJURY ACT: VACCINE INJURY TABLE (2008), <http://www.hrsa.gov/vaccinecompensation/pdfs-do-not-use/vaccineinjurytable.pdf>. Updates to the Vaccine Injury Table are also codified in the *Code of Federal Regulations*. See, e.g., 42 C.F.R. § 100.3 (2010).

Program began, the overwhelming majority of cases that were litigated in the program involved the relatively simple question of whether the Table requirements had been satisfied.¹⁹ However, the situation today, and for the foreseeable future, is the reverse. The overwhelming majority of cases litigated in the program do not involve Table injuries. In these cases, petitioners are asserting only non-Table claims and must prove that the vaccine caused the injury.

There are a number of reasons for this, but the most important is that the Table was substantially modified and narrowed by the Secretary of HHS in 1995 through an administrative rulemaking proceeding.²⁰ In addition, the nine vaccines added to the Table by the Secretary of HHS since 1988 generally have no specified Table injuries at all or have the immediate onset of anaphylactic shock as the only listed Table injury.²¹

These changes in the Table have resulted in other major changes in the operation of the program. The cases are now substantially more difficult, complex, and time-consuming to litigate. The science is less clear, and the special masters have much more difficult and complex scientific disputes to resolve than they did for the relatively simpler Table injury claims. Both petitioners' counsel and government counsel now need to search for experts in cutting-edge medical areas, such as genetics and neurology, where a great deal of uncertainty still exists. This contributes to a much more adversarial process than was supposed to exist in a program that was designed to be less adversarial.

The present focus of the Vaccine Program on virtually all off-Table cases has also resulted in a series of recent decisions from the U.S. Court of

19. The Vaccine Compensation Program's former Chief Special Master, Gary J. Golkiewicz, described how substantially the program had been changed by the 1995 Health and Human Services (HHS) Table changes:

With the enactment of the administrative Table amendments, effective Mar. 10, 1995, there was a dramatic shift in the percentage of cases decided pursuant to the Table versus those decided under an actual causation theory. While possessing no empirical data, experience and anecdotal evidence suggests that the percentages flip-flopped; prior to the amendments 90% of cases were Table cases, while after the amendments 90% of cases were actual causation cases. In fact, the undersigned has yet to adjudicate a case involving the interpretation of the amended Table; all litigated claims have been causation cases.

Stevens, 2001 WL 387418, at *8.

20. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7694 (Feb. 8, 1995) (codified at 42 C.F.R. § 100.3 (2011)).

21. The most recently added vaccines, which have no listed Table injuries, are the HPV vaccine, added in 2007; the seasonal flu vaccines, added in 2005; and the Hepatitis A vaccine, added in 2004. The only Table injury for several other vaccines, including the inactivated polio vaccine and the Hepatitis B vaccine, is anaphylactic shock within zero to four hours of receipt of the vaccine. See HEALTH RES. & SERVS. ADMIN., *supra* note 18.

Appeals for the Federal Circuit, purportedly clarifying but sometimes confusing the standards that the special masters are required to apply in deciding off-Table cases. A number of the Federal Circuit's recent rulings have observed that Congress intended compensation to be provided generously, and that "close calls regarding causation are [to be] resolved in favor of injured claimants."²² To the contrary, other recent Federal Circuit rulings have emphasized the importance of strict compliance with traditional tort standards of causation.²³ Such inconsistencies have illuminated the need for clear standards.

In this Article, I seek to evaluate what the Vaccine Compensation Program has accomplished and what it has not, assessing its evolution over the past two decades. I will also undertake a comparative assessment, evaluating the Vaccine Compensation Program in light of the experiences of other federal compensation programs that Congress has recently adopted.

Part I of this Article provides a brief history of the Vaccine Act and describes how the Act created a blend of inquisitorial and adversarial features for litigating vaccine cases. It then describes a number of the Vaccine Program's procedural and case management innovations. It also describes the major changes that have occurred in the program since it began in 1988, and the negative consequences that some of those changes have had on the way the program operates today. This Part also argues that there are a number of serious problems with the Vaccine Compensation Program that require systemic correction.

Part II briefly describes the five other major compensation programs that Congress has created since the passage of the Vaccine Act, each of which responded to a special circumstance: the Radiation Exposure Compensation Program (Radiation Program),²⁴ the Japanese-American internment compensation program,²⁵ the Smallpox Compensation Program,²⁶ the September 11th Victim Compensation Fund,²⁷ and the Countermeasures Injury Compensation Program.²⁸

22. *Andre v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009) (quoting *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325–26 (Fed. Cir. 2006); *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007) (quoting *Althen*, 418 F.3d at 1280).

23. *See, e.g., Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010), *reh'g en banc denied*, 380 F. App'x 142 (Fed. Cir. 2010).

24. Radiation Exposure Compensation Act, Pub. L. No. 101-426, 104 Stat. 920 (1990) (codified as amended at 42 U.S.C. § 2210 note (2006) (Radiation Exposure Compensation)).

25. Civil Liberties Act of 1988, Pub. L. No. 100-383, 102 Stat. 904 (codified as amended at 50 U.S.C. app. § 1989b (2006)).

26. Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-20, 117 Stat. 638 (codified at 42 U.S.C. § 239–239h (2006)).

Part III undertakes a comparative evaluation of these compensation programs. Several features of these newer programs, such as a reduced burden of proof for petitioners, could successfully be adopted to improve the Vaccine Compensation Program. Perhaps the most important lesson for the Vaccine Compensation Program, and for other compensation programs that Congress may adopt in the future, comes from the failed Smallpox Vaccination Program in 2002–2003, where a major reason for its failure was the perceived (and actual) inadequacy of its injury compensation plan.

Based upon both recent developments in the Vaccine Program and lessons learned from the other compensation plans, Part IV argues that a number of legislative and other measures should be undertaken to remedy the problems that exist in the Vaccine Compensation Program.

I. THE FLAWED FEDERAL VACCINE INJURY COMPENSATION PROGRAM

A. *History of the Vaccine Act and Its Key Provisions*

The federal vaccine injury compensation law, which took effect in 1988, was a pioneering example of no-fault federal tort reform legislation.²⁹ The specific provisions of the Act represented a legislative compromise among the major interest groups working on vaccine issues, including the vaccine manufacturers, physicians and healthcare groups, federal health agencies, and groups advocating on behalf of injured children. The compensation fund was part of a broader statute that also created new programs to increase the safety and availability of vaccines and provided vaccine manufacturers and healthcare providers with legal protections against lawsuits involving vaccine-induced injuries.³⁰

The Supreme Court in *Bruesewitz* described the Vaccine Act as involving a quid pro quo from the vaccine manufacturers, who received substantial

27. September 11th Victim Compensation Fund of 2001, Pub. L. No. 107-42, 115 Stat. 237 (2001) (codified as amended at 49 U.S.C. § 40101 note (2006) (Air Transportation Safety and System Stabilization)).

28. Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. § 247d-6d (2006)).

29. Vaccine Act, Pub. L. No. 99-660, 100 Stat. 3755 (1988) (codified as amended at 42 U.S.C. §§ 300a-1 to -34 (2006)).

30. 42 U.S.C. § 300aa-1 (2006). Now that *Bruesewitz* has eliminated all potential design defect claims against vaccine manufacturers, remaining claims that could be brought against manufacturers include claims based upon fraud, wrongful withholding of information about the safety or effectiveness of a vaccine, and manufacturing defects. See 42 U.S.C. § 300aa-22(b), -23(d)(2)(A) to (C); see also *Bruesewitz v. Wyeth L.L.C.*, 131 S. Ct. 1068, 1079–1080 (2011) (noting that judgments about vaccine design are properly left to the Food and Drug Administration (FDA)).

liability protection in return for establishing the Vaccine Injury Compensation Program that the “vaccine manufacturers fund from their sales.”³¹ While perhaps literally accurate, this statement is substantially misleading because the manufacturers contribute no money of their own to the fund, instead only transferring to the Vaccine Injury Compensation Trust Fund the excise taxes paid by others.³²

The Vaccine Act mandates that a claim for compensation from any person believed to have suffered a serious reaction to one of the vaccines recommended almost universally in the United States must be brought first in the U.S. Court of Federal Claims, in Washington, D.C. Claimants must litigate their cases through the Court of Federal Claims³³ before seeking other possible legal remedies against the manufacturer of the vaccine or the healthcare provider who administered it.³⁴ A claimant’s petition must assert that the vaccine either caused an injury from which the petitioner did not previously suffer, or that the vaccine “significantly aggravated” a pre-existing condition.³⁵ The petition must be filed in court prior to the expiration of the relatively short statute of limitations contained in the

31. *Bruesewitz*, 131 S. Ct. at 1080.

32. The Vaccine Compensation Fund obtains its funding from an excise tax levied on each vaccine dose administered. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 62 (1999). The tax is paid by either the private citizen who is vaccinated or by the federal government when it buys vaccines for free distribution under one of the government’s health and welfare programs. The current excise tax is \$0.75 per dose for each covered vaccine; some vaccines are two-, three-, or four-in-one shots that are then taxed at \$1.50, \$2.25, and \$3.00, respectively. *CDC Vaccine Price List*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Nov. 2, 2011), <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>.

33. To exhaust this remedy, the petitioner must receive a final decision on the merits from the special master, and then formally “reject” this decision. U.S. CT. OF FED. CLAIMS VACCINE R. 12(a)–(b). The petitioner can then file a civil action in state or federal court. 42 U.S.C. §§ 300aa-11(a)(1) to (2)(A), -21(a).

34. One of the compromises contained in the Vaccine Act made it more difficult for an injured person to subsequently bring a successful tort claim against a vaccine manufacturer by foreclosing manufacturer liability if the injury or death was “unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” 42 U.S.C. § 300aa-22(b)(1). The Supreme Court held in *Bruesewitz* that this provision barred all claims based upon design defects. 131 S. Ct. at 1080.

35. To establish a significant aggravation of a pre-existing condition, petitioner must show that he or she suffered a “change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa-33(4). The leading case explaining the criteria for a showing of significant aggravation is *Whitecotton v. Secretary of Health & Human Services*, 81 F.3d 1099, 1107–08 (Fed. Cir. 1996).

Act—thirty-six months from the first manifestation of the injury or twenty-four months from the time of death.³⁶

Vaccines play a vital role in protecting the health of the population as a whole,³⁷ resulting in what is generally recognized as one of the greatest public health successes of the past hundred years.³⁸ However, a relatively small percentage of people will suffer serious adverse effects from vaccines because no vaccine can be one hundred percent safe,³⁹ and vaccines are routinely given to tens of millions of Americans every year. Congress passed the Vaccine Act not only to encourage vaccination in America and to provide legal protection against vaccine-injury claims for vaccine manufacturers and healthcare providers, but also to create a safety net for those few who would be injured by the vaccinations so that compensation to injured petitioners would be provided “quickly, easily, and with certainty and generosity.”⁴⁰

Vaccinations usually begin shortly after a baby is born, before the infant leaves the hospital. The principal mechanism for enforcing mandatory vaccinations in America are laws in every state and the District of Columbia that generally require proof of childhood immunizations prior to entry into school or childcare centers.⁴¹ All of these statutes make exceptions for individuals who can certify that the vaccination is likely to cause death or serious injury. Most states also exempt persons with

36. 42 U.S.C. § 300aa-16(a). In a case brought by The George Washington University Law School Vaccine Injury Clinic, a divided panel of the U.S. Court of Appeals for the Federal Circuit held that the statute of limitations must be strictly applied, and was not subject to equitable tolling for any reason. *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1373–74 (Fed. Cir. 2001), *cert. denied sub nom. Brice v. Thompson*, 534 U.S. 1040 (2001). The Federal Circuit, sitting en banc, recently overruled *Brice* and held that equitable tolling is available under the Vaccine Act in appropriate situations. *See Cloer v. Sec'y of Health & Human Servs.*, No. 2009–5052, 2011 WL 3374302, at *15–18 (Fed. Cir. Aug. 5, 2011).

37. *See H.R. REP. NO. 99-908*, pt. 1, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345 (“While most of the Nation’s children enjoy great benefit from immunization programs, a small but significant number have been gravely injured.”).

38. Rutkow et al., *supra* note 10, at 681 (“Vaccines are widely hailed as one of the greatest medical and public health accomplishments of the twentieth century.”).

39. Robert T. Chen, *Safety of Vaccines*, in VACCINES 1144, 1144 (Stanley A. Plotkin & Walter A. Orenstein eds., 3d ed. 1999); *see also* Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1306–07 (Fed. Cir. 1999) (“Childhood vaccinations, though an important part of the public health program, are not without risk. Because vaccines often contain either killed bacteria or live but weakened viruses, they can cause serious adverse effects.”).

40. H.R. REP. NO. 99-908, pt. 1, at 3, reprinted in 1986 U.S.C.C.A.N. 6344, 6344.

41. Timothy J. Aspinwall, *Religious Exemptions to Childhood Immunization Statutes: Reaching for a More Optimal Balance Between Religious Freedom and Public Health*, 29 LOY. U. CHI. L.J. 109, 109 (1997); *see also* Vaccine Law Information, NAT'L VACCINE INFO. CTR., <http://www.nvic.org/vaccine-laws.aspx> (last visited Sept. 20, 2011).

religious objections to vaccinations, and a minority of states exempt persons with moral or philosophical objections to immunization.⁴² The scope of these exemptions, and the enforcement policies, vary substantially from state to state.⁴³

In the Vaccine Compensation Program's early years, the overwhelming majority of the cases brought, and compensation awarded, involved injuries to children. This has changed dramatically, and in the past few years the majority of cases brought, and awards made, have involved adults.⁴⁴

The procedures to be followed in adjudicating vaccine cases are set forth in the Vaccine Act, in the Vaccine Rules adopted by the judges of the U.S. Court of Federal Claims, and in the Guidelines for Practice adopted by the special masters.⁴⁵ The petition for compensation, in contrast to a complaint typically filed in a civil case, should not be a formalistic document that merely tracks statutory language, but instead should be a "short and plain statement" of the facts and the grounds for compensation.⁴⁶ The petition must be accompanied by all medical records that might possibly shed light on the case, including all available prenatal and pediatric records for an infant petitioner, affidavits from any persons who might be called to testify in the case, and medical expert opinions (if appropriate) from the medical experts that petitioner intends to rely upon in the case.⁴⁷ The respondent then files a report replying to the petition, which similarly should not be a

42. Aspinwall, *supra* note 41, at 109 & n.1 (referring to the great majority of states allowing religious exemptions); *see also* *Vaccine Law Information*, *supra* note 41. In 1905, the U.S. Supreme Court upheld the constitutionality of imposing a criminal conviction for failing to comply with a mandatory vaccination law involving the smallpox vaccine. *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905).

43. *See Vaccine Law Information*, *supra* note 41.

44. Dee Lord, Chief Special Master, U.S. Court of Fed. Claims, Evolving Caseload of the Office of Special Masters (Oct. 2010) (unpublished presentation) (on file with Author) (covering 1995–2010); *Statistics Report*, HUMAN RES. & SERVS. ADMIN., <http://www.hrsa.gov/vaccinecompensation/statisticsreports.html> (last visited Sept. 20, 2011) (covering 1989–2011). The principal reason for this change appears to be the addition of seasonal flu vaccines to the Vaccine Act in 2005, and the widespread use of these vaccines by adults. *Id.* A total of 2,713 awards have been made in the Vaccine Compensation Program through September 9, 2011. *Id.*

45. The Vaccine Rules originally took effect in 1990. Haupley & Mason, *supra* note 10, at 453.

46. U.S. CT. OF FED. CLAIMS VACCINE R. 2(c)(1)(A).

47. *See* 42 U.S.C. § 300aa-11(c)(2) (2006); OFFICE OF SPECIAL MASTERS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM § II(B) (2004) [hereinafter GUIDELINES FOR PRACTICE]. New Vaccine Rules, effective July 15, 2011, require all medical records to be filed electronically, after the petition for compensation is filed, except for pro se cases and other special circumstances. *See* U.S. CT. OF FED. CLAIMS VACCINE R. 17(b)(3).

mere formalistic opposition to the petition, but should include only those medical or other issues that respondent intends to contest.⁴⁸ Respondent's report must be accompanied by all medical expert reports that respondent will rely upon in the case.⁴⁹ The special master is then statutorily bound to issue a final decision in the case within 240 days of the date that the petition was filed.⁵⁰ This procedure sounds straightforward, but in practice the cases rarely proceed so smoothly, for the reasons discussed below.

B. The Vaccine Injury Table and Its Significance in the Program

Among the key legislative compromises, and the central innovative provision of the Vaccine Act, was the creation of the Vaccine Injury Table. This Table represents the substantive law that would be used to adjudicate most cases. All vaccines covered by the Vaccine Act are listed on this Table. The Table also lists the specific injuries recognized as presumptively related to the vaccine, and for each listed injury, the Table specifies a time limit for the onset of that injury.⁵¹ If a petitioner can show that a specified injury more likely than not occurred in the specified time frame after receipt of the vaccine, a presumption is created that the vaccine caused the injury, and petitioner is relieved of the often difficult burden of introducing medical proof that the vaccine did in fact cause the injury.⁵²

If petitioner makes this showing, the burden then shifts to the government to show, by a preponderance of evidence, that another cause (a factor unrelated to the vaccine) is the real source of the injury.⁵³ Unless the government can make this showing—rebutting the presumption that the vaccine caused the injury—the petitioner will prevail in the case. The statute also provides that the government cannot base its rebuttal on an idiopathic cause—a cause of unknown origin.⁵⁴

The original Table adopted by Congress contained ten vaccines: measles, mumps, and rubella (commonly given together as an MMR shot); diphtheria, tetanus, and pertussis (commonly given together as a DTP shot); and the two polio vaccines (IPV and OPV).⁵⁵ The current Table contains

48. U.S. CT. OF FED. CLAIMS VACCINE R. 4(c).

49. *Id.* R. 4(c)(2); GUIDELINES FOR PRACTICE, *supra* note 47, at § IV.

50. 42 U.S.C. § 300aa-12(g); U.S. CT. OF FED. CLAIMS VACCINE R. 10(b).

51. 42 U.S.C. § 300aa-14(a); see also HEALTH RES. & SERVS. ADMIN., *supra* note 18.

52. See 42 U.S.C. § 300aa-11.

53. *Id.* § 300aa-13(a)(1)(B).

54. *Id.* § 300aa-13(a)(2)(A). Sudden Infant Death Syndrome (SIDS) is such an idiopathic cause. *Doe v. Sec'y of the Dep't of Health & Human Servs.*, 83 Fed. Cl. 157, 159 (2008); *Davis v. Sec'y of the Dep't of Health & Human Servs.*, 54 Fed. Cl. 230, 235 (2002).

55. Vaccine Act, Pub. L. No. 99-660, § 2114(a), 100 Stat. 3755, 3764–65 (1986) (codified as amended at 42 U.S.C. § 300aa-14(a)).

these ten vaccines and nine additional vaccines that were added to the Table in the years since the Act was adopted.⁵⁶

The Table was intended to play a central role in resolving cases in the Vaccine Program for several reasons. First, there is still a great deal of scientific uncertainty concerning the nature of potential vaccine-related injuries. Although there are a few definitive conclusions that can be made about vaccine-induced injuries,⁵⁷ there are many more areas where the illnesses or diseases are poorly understood. The relationship between the diseases and vaccines has not been thoroughly investigated.⁵⁸ Definitive answers about whether a vaccine caused an injury are often impossible to make in a specific case.⁵⁹

56. These vaccines are: Hepatitis A and B, HPV, seasonal flu vaccines, meningococcal, pneumococcal conjugate, rotavirus, and varicella (chicken pox). HEALTH RES. & SERVS. ADMIN, *supra* note 18.

57. For example, the now-discontinued oral polio vaccine caused a limited number of paralytic polio cases in the United States. This vaccine used live, attenuated viruses, causing an estimated eight to ten cases of polio in America each year, out of millions of doses given. To eliminate these injuries, the United States switched several years ago to the inactivated or killed polio virus vaccine, even though the killed vaccine was less effective in a number of ways. *See Peter Paradiso & Peter Wright, Oral Poliovirus Vaccine Only, in OPTIONS FOR POLIOMYELITIS VACCINATION IN THE UNITED STATES: WORKSHOP SUMMARY* 14, 16 (Cynthia J. Howe & Richard B. Johnstone eds., 1996); Frederick Robbins & Walter Orenstein, *U.S. Experience, in OPTIONS FOR POLIOMYELITIS VACCINATION IN THE UNITED STATES: WORKSHOP SUMMARY, supra*, at 3; *Poliomyelitis Prevention in the United States: Updated Recommendation of the Advisory Committee on Immunization Practices (ACIP)*, MORBIDITY & MORTALITY WKLY. REP., May 19, 2000, at 2.

58. The Federal Circuit has described the vaccine injury area as “a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). The Centers for Disease Control and Prevention’s (CDC’s) Vaccine Information Statements (VIS) acknowledge serious acute consequences from a number of vaccines, including the following “Moderate Problems” from the current diphtheria, tetanus, and pertussis (DTaP) vaccination: “Seizure (jerking or staring) (about 1 child out of 14,000)”; “Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)”; “High fever, over 105°F (about 1 child out of 16,000).” CTRS. FOR DISEASE CONTROL & PREVENTION, DIPHTHERIA, TETANUS & PERTUSSIS VACCINES: WHAT YOU NEED TO KNOW (2007). However, the VIS fail to acknowledge any chronic problems caused by the vaccines. For example, the CDC’s VIS on DTaP states, “Several other severe problems have been reported after DTaP,” including “long-term seizures” and “permanent brain damage.” *Id.* The VIS concludes that these problems “are so rare it is hard to tell if they are caused by the vaccine.” *Id.*

59. There are generally no definitive biological markers to prove that a vaccine was the cause of an injury, except for rare cases like the now-discontinued live polio vaccine. It is often impossible to determine conclusively that a person suffered the onset of a disease or illness as a result of a vaccine, as opposed to an illness that was caused by other, often unknown reasons. The fact that an adverse event occurred after a vaccination is not, in itself, proof that the vaccine caused the adverse event, but it is suggestive of such an effect.

Moreover, litigation in Table cases is relatively simple. The focus in these cases is first on whether the injury alleged is the injury specified in the Table. While there have been cases where medical experts disagreed on the nature of the injury involved in the vaccine injury claim, most of the time there will be no substantial dispute on the nature of the injury or on the date of onset for the claimed injury. While experts sometimes disagree about which symptoms represent the date of onset of the claimed injury, in the great majority of cases the medical and hospitalization records sufficiently document the nature of the injury and the date of its onset. Thus, in Table injury cases, the medical and scientific issues involving the nature of the injury and the onset of its first manifestation would generally not be expected to create serious difficulties for the resolution of cases in the vaccine program. In most cases it would be expected that the doctors would agree on the nature of the injury and its likely date of onset. Even in rarer cases where issues are disputed, the scientific matters requiring resolution by the special masters are relatively easy to decide.⁶⁰

The use of the Table is also essential to the expeditious and efficient processing of vaccine injury claims. As a former special master in the vaccine program, Denis J. Hauptly, along with his co-author, wrote:

“[T]his type of program only works when issues can be converted into formulas to a significant degree. That is, the use of the “table” to establish presumptive causation in vaccine cases makes it possible to handle most cases with minimal effort.”⁶¹

In vaccine cases where no Table injury claim can be made, the special masters have much more difficult and complex issues to decide. In such off-Table cases, the special masters must base their decisions on medical opinions or published articles linking the vaccine to the injury involved in the case. These off-Table cases often involve complex medical questions about which there is likely to be no definitive consensus among experts.

This has become a particular problem for the Vaccine Program because of the dramatic shift from the early years of the program, 1989 to 1992, when more than 90% of the petitions filed asserted Table injuries, to the most recent years, 2007 to 2010, when almost 90% of the petitions filed assert only non-Table injuries.⁶²

See Neal A. Halsey, *The Science of Evaluation of Adverse Events Associated with Vaccination*, 13 SEMINARS IN PEDIATRIC INFECTIOUS DISEASES 205, 207 (2002).

60. *See* 42 U.S.C. § 300aa-13(b).

61. Hauptly & Mason, *supra* note 10, at 457.

62. *See* Stevens v. Sec'y of the Dep't of Health & Human Servs., No. 99-594V, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001).

C. Major Changes in the Table and the Program and Their Consequences

The National Vaccine Injury Compensation Program changed substantially in 1995, when the Secretary of HHS announced modifications to the Vaccine Injury Table that would drastically change not only the Table, but also the nature of the Vaccine Compensation Program. The Table changes have in effect created a new and different vaccine compensation program.

This change in the Table also affected Hannah Bruesewitz's case. Hannah's parents filed their petition for compensation in the U.S. Court of Federal Claims in April of 1995, one month after the new Vaccine Injury Table,⁶³ which eliminated residual seizure disorder as a Table injury, went into effect. Hannah had a strong claim of a residual seizure disorder under the prior table;⁶⁴ but unfortunately for her family this Table injury had been eliminated. The special master ruled that Hannah had not proven that she either suffered an injury recognized by the Vaccine Injury Table in effect at the time she filed her case, or that her seizure disorder and related problems were caused in fact by the DTP vaccines she received.⁶⁵

In 1995, because of the administrative rulemaking proceeding instituted by the Secretary of HHS⁶⁶ that modified both the Table and the Qualifications and Aides to Interpretation (QAI) of the Table, the Table was substantially narrowed.⁶⁷ The two most important changes that affected the largest number of people were the elimination of residual seizure disorder and hypotonic hyporesponsive episode (HHE) as Table

63. 42 C.F.R. § 100.3 (1995).

64. To establish a residual seizure disorder under the original Vaccine Injury Table, Hannah would have had to show that she suffered her first seizure within three days of her DTP vaccination and suffered two or more seizures within one year that were essentially afebrile. 42 U.S.C. § 300aa-14(a), (b)(2)(B) (1988).

65. *Bruesewitz v. Sec'y of the Dep't of Health & Human Servs.*, No. 95-0266V, 2002 WL 31965744, at *17 (Fed. Cl. Dec. 20, 2002).

66. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678 (Feb. 8, 1995).

67. 42 C.F.R. § 100.3 (2010). The Vaccine Act gave the Secretary of HHS the authority to modify the Table, as agency officials are often empowered by Congress to modify the regulations they implement. *See* 42 U.S.C. § 300aa-14(c), (e)(2) (2006). The authority of the Secretary of HHS to make the 1995 Table changes was challenged in the U.S. Court of Appeals for the Federal Circuit in *Terran v. Secretary of Health & Human Services*, 195 F.3d 1302 (Fed. Cir. 1999). A divided panel of the court upheld the authority of the Secretary of HHS to make the 1995 Table changes, rejecting arguments that the changes violated the Constitution's Presentment Clause and were an unlawful delegation of legislative authority to an administrative official to amend a statute. *Id.* at 1314–15. Judge Plager dissented on the ground that the 1995 changes violated the Presentment Clause. *Id.* at 1317.

injuries,⁶⁸ and the redefining of the Table injury of encephalopathy from a broad, inclusive definition to a hyper-technical and narrow definition that is extremely difficult, if not impossible, to satisfy.⁶⁹ Moreover, as noted above, practically all of the vaccines added to the Table in recent years have either no specified Table injuries, or else they have only the listed injury of an immediate anaphylactic shock reaction.⁷⁰

The Secretary of HHS based the 1995 Table changes largely on a then-recent report from the Institute of Medicine.⁷¹ Several persons who submitted comments to the Secretary on the proposed new Table pointed out that the Secretary had not considered the results of several large databases on vaccine injuries, and urged the Secretary to wait for more definitive information before modifying the Table.⁷² The Secretary responded that it was unnecessary for the information it relied upon to be “definite and conclusive before any changes are made.”⁷³ Several persons also submitted comments indicating that the 1995 rule change would substantially change the nature of the Vaccine Injury Compensation Program, but the Secretary responded that “the benefits of the proposed regulation outweigh the possibility of more protracted and complex hearings.”⁷⁴

68. The Table changes substantially reduced the proportion of compensated petitioners. This point is dramatically made by the fact that 45% of all claims that had been awarded compensation as of 1999 involved injuries later dropped from the Table. Clearly, changes to the Table by the Secretary drastically altered the prospect for compensation for large numbers of petitioners.

Jeffrey A. McLellan, Note, *The Constitutional Challenge to the Vaccine Act in Terran v. Secretary of Health & Human Services and its Policy Implications*, 12 FED. CIR. B.J. 687, 692 (2004) (footnotes omitted).

69. *Encephalopathy* was initially defined broadly as any “injury to, or impairment of function of the brain.” 42 U.S.C. § 300aa-14(b)(3)(A) (1988). The 1995 amendment to the Table redefined it much more narrowly to include only those injuries that satisfied the criteria for an acute and then a chronic encephalopathy. 42 C.F.R. § 100.3(b)(2) (1995). An acute encephalopathy requires a “significantly decreased level of consciousness” for more than twenty-four hours, and a chronic encephalopathy requires a “change in mental or neurologic status, first manifested during the applicable time period, persist[ing] for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event.” *Id.* § 100.3(b)(2)(i)(A), (b)(ii).

70. Stevens v. Sec'y of the Dep't of Health & Human Servs., No. 99-594V, 2001 WL 387418, at *8 n.11 (Fed. Cl. Mar. 30, 2001), abrogated in part by Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1281 (Fed. Cir. 2005).

71. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995) (codified at 42 C.F.R. pt. 100).

72. *Id.* at 7681, 7685–86.

73. *Id.* at 7681.

74. *Id.* at 7682.

According to former Chief Special Master Gary J. Golkiewicz, the 1995 rule change did produce a tremendous change in the nature of the vaccine claims litigated in the program.⁷⁵ In the first few years, practically all cases involved only satisfying the Table requirements and adjudicating whether another factor unrelated to the vaccine was the likely cause of the injury. With the changes in the Table and the subsequent addition of many new vaccines without any Table injuries, the focus of vaccine case adjudication is now dramatically different. Ninety percent of vaccine cases are now causation-in-fact cases.⁷⁶ The Table was intended to be a crucial innovation, a key to the quick, hospitable, and less adversarial Vaccine Act proceedings. It is now central to only a small minority of cases. The Table has little significance in resolving the overwhelming majority of vaccine cases that come before the court today.

The recent focus on causation-in-fact cases has also generated other major changes in the nature of the Vaccine Injury Program. First, the cases are substantially more difficult and complex to litigate. The special masters have much more challenging scientific disputes to resolve in these cases than they do for Table claims.

Second, both sides need to locate experts in cutting-edge areas, where substantial uncertainty still exists. For the old Table injuries, a neurologist would testify whether a petitioner's injury did or did not meet the definition of encephalopathy listed in the Table, and its Qualifications and Aides to Interpretation, and whether the onset of the injury did or did not occur within the time period required by the Table. In off-Table cases, the experts now have to present much more complex testimony concerning whether the vaccine was the likely cause of the problems that the petitioner subsequently experienced.

The complex off-Table cases that now predominate in the Vaccine Compensation Program also proceed more slowly than the simpler Table injury cases, and typically result in more adversarial litigation than Table cases because the parties and their experts usually begin from polar opposite positions. The relatively easy question of determining whether an injury satisfies the Table criteria has become the much more difficult question of whether a vaccine in fact caused an injury. These changes have encouraged the type of adversarial litigation that the Vaccine Act was designed to minimize.

The result of these changes is that the Vaccine Compensation Program today is not at all like the program that the Supreme Court described in *Bruesewitz* as involving "fast, informal adjudication," focusing on Vaccine

75. *Stevens*, 2001 WL 387418, at *8.

76. *Id.*

Injury Table requirements.⁷⁷ Instead, it is a much slower and more adversarial process that focuses on formally adjudicating non-Table causation-in-fact cases.

The shift in focus to off-Table cases has also led to the creation of several “omnibus proceedings,” in which the special masters consolidate a number of similar cases into one proceeding. The largest and most controversial omnibus proceeding is the ongoing proceeding concerning autism, which involves more than 5,000 petitioners. Other omnibus proceedings have involved the rubella vaccine and arthritic conditions, the hepatitis B vaccine, and other vaccines.⁷⁸

A final important consequence of the massive switch to off-Table cases has been a series of decisions from the U.S. Court of Appeals for the Federal Circuit, beginning in 2005, which have attempted to clarify the legal standards for proving causation-in-fact cases.⁷⁹ Under the principles enunciated in these cases, petitioners’ burden in off-Table cases is to demonstrate that a vaccine was a substantial factor in causing an injury, but not necessarily the sole or even the predominant factor causing the injury.⁸⁰ Petitioners must also demonstrate that the vaccine was a “but for” cause of the injury, in that the injury would not have occurred except for the administration of the vaccine.⁸¹ Petitioners are not required to prove that a specific biological mechanism was the means by which the vaccine caused the injury, and are also not required to show that all other possible causes for the injury have been eliminated.⁸² In *Althen v. Secretary of Health & Human Services*, the Federal Circuit specified that to satisfy these burdens, petitioners must demonstrate: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”⁸³

These legal standards are noncontroversial and widely accepted. However, a controversy emerged from a line of Federal Circuit cases that

77. *Bruesewitz v. Wyeth L.L.C.*, 131 S. Ct. 1068, 1073 (2011).

78. *See infra* Part II.E.4.

79. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009); *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146 (Fed. Cir. 2007); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352 (Fed. Cir. 2006); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

80. *Althen*, 418 F.3d at 1278.

81. *Id.*

82. *Walther*, 485 F.3d at 1150; *Capizzano*, 440 F.3d at 1324; *Knudsen v. Sec'y of the Dep't of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994).

83. *Althen*, 418 F.3d at 1278.

began with *Althen* in 2005, continued in *Walther v. Secretary of Health & Human Services* in 2007, and included *Andreu v. Secretary of Health & Human Services* in 2009. In these cases, the Federal Circuit emphasized that “close calls regarding causation are [to be] resolved in favor of injured claimants.”⁸⁴ Such a rule is consistent with Congress’s intent that the vaccine law create a generous compensation program that was to be liberally construed in favor of compensating injured petitioners.⁸⁵ However, a second line of cases, including *De Bazan v. Secretary of Health & Human Services* in 2008 and *Moberly v. Secretary of Health & Human Services* in 2010, takes a very different perspective, emphasizing that traditional tort standards should be strictly applied to off-Table cases.⁸⁶ These cases treat the Vaccine Act as if it were a waiver of sovereign immunity, calling for legal principles that require the courts to strictly construe the Act against petitioners.

It is striking that *Andreu* and *Moberly* reached such divergent conclusions, as they were so factually similar. In both cases, young children developed seizure disorders shortly after receipt of a DTP vaccination. In *Andreu*, the onset of the seizure disorder was one day; in *Moberly* it was two days.⁸⁷

In *Andreu*, the petitioner’s vaccine expert and the child’s neurologist both testified that the vaccine likely caused the seizure disorder, and the government’s expert testified that, while he did not agree that the vaccine caused the seizure disorder, he did not contest the biological plausibility of that view.⁸⁸ The Federal Circuit held that petitioner had satisfied the applicable burdens under *Althen* and ordered that compensation be paid.⁸⁹ In *Moberly*, the Federal Circuit affirmed the special master’s denial of compensation and distinguished *Andreu* on two grounds.⁹⁰ First, the *Moberly* court pointed out that in *Andreu* the treating physician supported the vaccine–injury link, while in *Moberly* the principal treating physician was not supportive but was instead skeptical of the vaccine–injury link.⁹¹ Second, the court noted that in *Andreu* the government’s expert witness had

84. *Andreu*, 569 F.3d at 1378 (quoting *Cappizano*, 440 F.3d at 1325–26); *Walther*, 485 F.3d at 1150 (quoting *Althen*, 418 F.3d at 1280).

85. See *Andreu*, 569 F.3d at 1378 (stating that requiring epidemiological studies or generally accepted medical principles would impermissibly raise a claimant’s burden).

86. *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322–23 (Fed. Cir. 2010); *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); see also *Grant v. Sec’y of the Dep’t of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

87. *Moberly*, 592 F.3d at 1318; *Andreu*, 569 F.3d at 1370.

88. See *Moberly*, 592 F.3d at 1325.

89. *Andreu*, 569 F.3d at 1370.

90. *Moberly*, 592 F.3d at 1325.

91. *Id.*

not contested the biological plausibility of the vaccine-injury link, while in *Moberly* the government's expert did contest the biological plausibility of this link.⁹² These distinctions confuse rather than clarify the law.

One crucial consideration for the special masters should not be whether the current principal treating physician supports a vaccine injury link. Instead, the key consideration should be the weight and authority behind the views of the expert witnesses who testify in the case. Similarly, another crucial consideration for the special masters should not be whether the government's expert accepts the plausibility of the petitioner's proposed vaccine injury link. Instead, the key consideration should be the extent of the agreement and disagreement between the experts who testify on both sides and the strength of the grounds in support of the experts' views. The Federal Circuit's two bases to distinguish *Moberly* from *Andreu* are unhelpful at best in giving guidance to the special masters or the parties who appear before them.

Unfortunately, the Federal Circuit denied en banc review in *Moberly*,⁹³ leaving in place substantial uncertainty regarding the appropriate legal standards to apply in off-Table cases. Further action from the Federal Circuit, the Supreme Court, or Congress will be needed to remedy this serious problem and bring clarity to the law that should be applied in off-Table cases.

After the Vaccine Compensation Program had been operating for a decade, three major U.S. government organizations evaluated and published reports on the program—the Federal Judicial Center,⁹⁴ the U.S. Government Accountability Office (GAO),⁹⁵ and the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources.⁹⁶ The three reports raised similar concerns about the operation of the Vaccine Program, including delays in resolving cases that stretched far beyond the statutory 240-day limit,⁹⁷ and the overly adversarial nature of the cases in a compensation program intended to be less adversarial.⁹⁸ All three reports

92. *Id.*

93. *Moberly v. Sec'y of Health & Human Servs.*, 380 F. App'x 142 (Fed. Cir. 2010).

94. MOLLY TREADBURY JOHNSON ET AL., FED. JUDICIAL CTR., USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (1998).

95. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/HEHS-00-8, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY (1999) [hereinafter GAO VACCINE COMPENSATION REPORT].

96. H.R. REP. NO. 106-977 (2000).

97. *Id.* at 12; GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 2; JOHNSON ET AL., *supra* note 94, at 5.

98. H.R. REP. NO. 106-977, at 2; GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 3; JOHNSON ET AL., *supra* note 94, at 5.

also noted concerns about payment of attorneys' fees, including concerns that the fees were too low, took too long to process, and were subject to unnecessarily adversarial review by Department of Justice (DOJ) attorneys.⁹⁹ These same concerns have continued to be raised by others,¹⁰⁰ and they remain valid today. Problems with delays and the overly adversarial nature of the program have been exacerbated by the change in the Vaccine Table and the related developments described above.

Other problems that have been noted with the Vaccine Program include the short, inflexible three-year statute of limitations to file a claim in the program; the low \$250,000 award for death cases; the low \$250,000 cap on pain and suffering in injury cases; and the burden of proof imposed on petitioners in off-Table cases.¹⁰¹ Part IV of this Article proposes specific steps to try to correct these problems.

D. The Special Masters' Role in the Decisionmaking Process

The Vaccine Act created a partially inquisitorial and partially adversarial process for adjudicating vaccine injury claims.¹⁰² The special

99. H.R. REP. NO. 106-977, at 17; GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 11; JOHNSON ET AL., *supra* note 94, at 5; see also Besty J. Grey, *The Plague of Causation in the National Childhood Vaccine Injury Act*, 48 HARV. J. ON LEGIS. 343, 355 n.87 (2011) (noting that the Act encourages use of the Vaccine Program because fees are awarded even when the petitioning party fails to qualify for compensation, as long as the petition was brought in good faith).

100. See, e.g., Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J.L. & PUB. POL'Y 537, 635–36 (2010) (arguing for a totally new holistic framework for vaccine injury compensation); Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 319–20 (1999); Brittani Scott Miller, Note, *The National Childhood Vaccine Injury Compensation Program: The Unavailability of Experienced Attorneys Places Petitioners at an Institutional Disadvantage*, 19 FED. CIR. B.J. 253, 272 (2010); Ridgway, *supra* note 32, at 74 (“No aspect of the [National Vaccine Injury Compensation Program] has been more intensively disputed than the awarding of attorney fees.”); Elizabeth C. Scott, Comment, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 362 (2001); Lisa J. Steel, Note, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?*, 63 GEO. WASH. L. REV. 144, 170–71 (1994) (discussing the lack of definitive evidence in the vaccine injury area).

101. Apolinsky & Van Detta, *supra* note 100, at 580; Breen, *supra* note 100, at 319–20; Miller, *supra* note 100, at 172; Scott, *supra* note 100, at 361; Steel, *supra* note 100, at 170.

102. American legal procedures are said to flow from the British common law adversarial tradition, in contrast to the legal procedures used in the inquisitorial tradition of continental Europe. See Amalia D. Kessler, *Our Inquisitorial Tradition: Equity Procedure, Due Process, and the Search for an Alternative to the Adversarial*, 90 CORNELL L. REV. 1181, 1198–1210 (2005) (detailing the development of the common law in the United States). Although all court systems seem to combine some elements of both models, *id.* at 1187, the two contrasting models have been described as follows:

masters have much greater control and responsibility in processing cases than a state or federal judge has in the typical civil case. The special masters are given authority to participate actively in the cases and to structure the process for each case. They are not expected to play the neutral umpire's role as are judges in other sorts of civil litigation.¹⁰³ This model of the decisionmaker in an adversarial system is one of a largely passive receiver of information who listens to what both sides have to say and then renders a decision based only on the most persuasive evidence introduced and the arguments made by counsel.¹⁰⁴

In the adversarial model, the parties are responsible for . . . conducting the litigation. They gather all the evidence and present it orally, in open court, subjecting witnesses to examination and cross-examination, and the court serves as a neutral umpire, deciding questions of fact and law raised by the parties. In addition, the parties bear primary responsibility for determining the sequence and manner in which evidence is presented and legal issues are argued. In contrast, in the inquisitorial model, the court . . . undertakes significant responsibility for gathering evidence, not just for ruling on the conclusions that should be drawn from it . . . Furthermore, the court is largely responsible for determining the sequence and manner in which issues of fact and law are considered and decided.

Id. at 1188 (footnotes omitted); see also Ellen E. Sward, *Values, Ideology, and the Evolution of the Adversary System*, 64 IND. L.J. 301, 313–14 (1989). In the inquisitorial model, the decisionmaker can be the individual who initiates the litigation, as opposed to one of the parties. *Id.* at 313. The inquisitorial model relies more heavily on written documents, such as witness affidavits obtained by the investigating magistrate, as opposed to relying largely on oral testimony from witnesses introduced in court hearings by counsel for the parties. *Id.* at 314.

103. GUIDELINES FOR PRACTICE, *supra* note 47, at § V; U.S. CT. OF FED. CLAIMS VACCINE R. 3(b). See generally United States v. Marzano, 149 F.2d 923, 926 (2d Cir. 1945); Robinson v. United States, 513 A.2d 218, 220 (D.C. Cir. 1986).

104. The Guidelines for Practice and the Vaccine Rules describe the many informal, inquisitorial procedures that the program employs, including an informal off-the-record status conference shortly after the petition and respondent's report are filed, pursuant to Vaccine Rule 5. At this conference the special master “(1) gives each party an opportunity to address the other's position, (2) states a tentative view on the merits of the case, and (3) establishes with the parties what issues remain to be addressed and the most efficient means for deciding those issues.” GUIDELINES FOR PRACTICE, *supra* note 47, at § VI. The Guidelines continue:

The special master will be more actively involved in the early stages of proceedings than is usually the case with a judge in a traditional civil proceeding, e.g., identifying and assisting a party in obtaining information, making tentative findings where appropriate . . . Further, in recognition of Congress's intent that the special masters be more “inquisitorial” than in typical litigation, the special master will question witnesses where appropriate, ask for more documents when such a need is determined, and keep the parties informed at all stages concerning what further proof is necessary to prove their cases.

Id. at § V. Special masters are given the authority to receive evidence in person, by telephone, or in writing; there is no right of parties to cross-examine witnesses, and neither

In contrast to this familiar image, the special masters were intended to be expert decisionmakers¹⁰⁵ with substantial knowledge of vaccine injuries and substantial authority to structure how each case proceeds.¹⁰⁶ The Vaccine Act also mandates procedural rules that “provide for a less-adversarial, expeditious, and informal proceeding”¹⁰⁷ which will have “flexible and informal standards of admissibility of evidence.”¹⁰⁸

The Vaccine Act, as originally passed by Congress, gave the special masters the more limited role of only making proposed findings of fact, proposed conclusions of law, and recommended decision to a judge of the U.S. Court of Federal Claims, who would then make the actual decision in the case.¹⁰⁹ The judges would often give substantial deference to the findings and proposed decision of the special master who presided over the evidentiary hearing in the case.¹¹⁰

A few years later, an amendment to the Vaccine Act changed this situation, giving the special masters full authority, like any trial judge or administrative law judge, to issue decisions.¹¹¹ This created an unusual structure in the Court of Federal Claims. The Office of Special Masters is an “adjunct” to the Court. The special masters now make all final decisions, which are subject to review first by a judge of the Court of Federal Claims,¹¹² then by the U.S. Court of Appeals for the Federal

the Federal Rules of Evidence nor the Federal Rules of Civil Procedure apply. Vaccine Rule 8(b) provides: “In receiving evidence, the special master will not be bound by common law or statutory rules of evidence” U.S. CT. OF FED. CLAIMS VACCINE R. 8(b)(1).

105. See JOHNSON ET AL., *supra* note 94, at 14–15 (stating that even though Congress envisioned some nonlawyer scientists serving as special masters, all special masters have had a law degree).

106. There is always a tension between the desirability of having an expert decisionmaker, who can bring specialized knowledge and experience in the area, and the problems that can arise, such as when the expert decisionmaker can become biased or come to regard himself or herself as the “real” expert who has heard many similar cases before, and will only use the testimony received from the medical experts who testify at hearings insofar as that testimony supports the special master’s preexisting positions. See Sward, *supra* note 102, at 338–39. Similar tensions exist for decision makers on other specialized courts, such as bankruptcy and tax courts on the federal level, and in probate, family, and other special courts at the state level. *Id.* at 338 & n.197.

107. 42 U.S.C. § 300aa-12(d)(2)(A) (2006).

108. *Id.* § 300aa-12(d)(2)(B).

109. Hauptly & Mason, *supra* note 10, at 452.

110. The Claims Court judge could accept the special master’s recommendations in whole or in part, remand the decision with instructions, or undertake de novo review. *Id.* at 457 n.19.

111. *Id.* at 452.

112. This puts the Claims Court judge in an unusual position, because in most other cases, the judge acts as the initial decisionmaker, but in vaccine cases, the judge acts as a reviewing authority.

Circuit, with discretionary certiorari review by the Supreme Court.¹¹³ Judges from the Court of Federal Claims and the Federal Circuit apply familiar principles of judicial review to special masters' decisions, giving substantial deference to findings of fact, credibility decisions, and discretionary judgments, but reviewing the special masters' application of principles of law *de novo*.¹¹⁴

In the first months of the Vaccine Compensation Program, the Department of Justice withdrew from all cases before the special masters, citing budgetary constraints.¹¹⁵ During this time, the vast majority of cases before the special masters proceeded without the Secretary of HHS being represented by counsel.¹¹⁶ These cases proceeded in a relatively informal and nonadversarial manner, with the special masters playing the largely inquisitorial role that Congress had envisioned for them. However, when the Department of Justice began representing HHS in 1989–1990, the relatively informal and nonadversarial nature of the litigation began to change substantially.¹¹⁷ The Department of Justice established a group of attorneys specializing in litigating these vaccine cases, and the HHS established both an in-house group of experts to evaluate vaccine injury claims and an outside group of expert witnesses to testify for the government in its defense of the cases.¹¹⁸ Since that time, there has been criticism that the vaccine cases have become too adversarial, and that the informal, inquisitorial manner in which the special masters had initially processed these cases has changed to a more traditional adversarial

113. 42 U.S.C. § 300aa-12(e)–(f). The Supreme Court has reviewed only one case on direct appeal from the vaccine court. *Shalala v. Whitecotton*, 514 U.S. 268 (1995). *Whitecotton* dealt with the standards for determining when the onset of the first manifestation of an illness occurred. *Id.* at 269.

114. The Vaccine Act contains the usual standards for judicial review, allowing the judge from the U.S. Court of Federal Claims or the Federal Circuit to “set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law.” 42 U.S.C. § 300aa-12(e)(2)(B). Findings of fact are reviewed under the deferential “arbitrary and capricious” standard. *See Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). Discretionary rulings are reviewed under a deferential “abuse of discretion” standard. *Saunders v. Sec'y of the Dep't of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994). Finally, conclusions of law are reviewed under the nondeferential *de novo* standard. *Id.*

115. Hauptly & Mason, *supra* note 10, at 457 n.21.

116. *See id.* (noting that the majority of cases proceeded *ex parte* with the respondent unrepresented).

117. In 1989, Congress urged the participants in the Vaccine Program to re-dedicate themselves to the nonadversarial resolution of cases. H.R. REP. NO. 101-386, at 512–13 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3115–16.

118. GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 10.

process.¹¹⁹ Off-Table cases, particularly, have become much more burdensome for petitioners and have moved more slowly, with very few cases actually decided within the statutory 240-day deadline for a final decision.¹²⁰

Another reason for delay in Vaccine Act cases is that they are generally bifurcated into two separate stages. In the first stage, the sole issue is whether the petitioner has proven entitlement to receive compensation for a vaccine injury. If petitioner is successful at this stage, the case then proceeds to the second stage, which involves a determination of the amount of compensation to be awarded. The damages stage is often complex and protracted and commonly exceeds, by itself, the 240-day statutory deadline for final resolution of the entire case.¹²¹

Delays in the Vaccine Program have been caused by counsel for petitioners as well as by counsel for the government for a number of reasons, including difficulties in obtaining medical records and expert reports. There can be times when it is advantageous for petitioner's counsel to seek delays, such as when petitioner's retained expert recommends new, time-consuming medical testing of the petitioner. Additionally, delay could be proper where it might be beneficial in preparing a life-care plan involving an infant to learn more over time about that infant's degree of impairment, and to get a better idea of the infant's likely future medical and therapeutic needs.

E. Procedural Innovations in the Vaccine Compensation Program

There are a number of successful procedural and case-management innovations that have been developed in the Vaccine Program, some as a result of mandates contained in the initial legislation and some as a result of innovative practices that the special masters have adopted over the years. Pretrial innovations such as front-loading of evidence and expert reports, and a variety of informal procedures such as telephonic "off the record"

119. Lawrence O. Gostin, *Medical Countermeasures for Pandemic Influenza: Ethics and the Law*, 295 J. AM. MED. ASS'N. 554, 555 (2006).

120. GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 2.

121. The Vaccine Act specifies the damages that can be awarded. When the vaccine reaction resulted in the death of the petitioner, a lump-sum payment in the amount of \$250,000 will be made to petitioner's estate. 42 U.S.C. § 300aa-15(a)(2) (2006). For vaccine-related injuries, the petitioner is entitled to receive payment for past and future pain and suffering (capped at \$250,000), future lost income, and reasonably necessary future medical, therapeutic, and related expenses. *Id.* § 300aa-15(a)(1), (3)-(4).

status conferences, have generally worked out well and could serve as a model in other types of litigation.¹²²

In many ways, the evidentiary hearings held before the special masters look like typical civil trials. Counsel for both sides may make opening statements and then introduce the testimony of fact witnesses, such as family members, as well as medical exhibits and testimony from medical experts. At the conclusion of the evidence, counsel may make closing arguments or may submit post-hearing briefs at a later date. While these trials look similar to other civil trials in some respects, they are also unique in several important ways. In this Author's opinion, the most important innovation is the wholesale integration by the special masters of the expert witnesses into the evidentiary hearings rather than the usual procedure of sequestering the expert witnesses when they are not testifying in open court.

1. The Expanded Role of Expert Witnesses at Hearings

The standard rule of procedure used in virtually all courtrooms in America, civil and criminal, is to exclude nontestifying witnesses from the courtroom while other witnesses in the case are testifying.¹²³ The "rule on witnesses," a rule that was hundreds of years old in the British judicial tradition when it was brought over to the American colonies, directs the removal or sequestration of all nontestifying witnesses so they cannot hear the testimony that other witnesses in the case give in court under oath. This sequestration procedure has been praised as "one of the greatest engines that the skill of man has ever invented for the detection of liars in a court of justice."¹²⁴

Rule 615 of the Federal Rules of Evidence gives the parties the right to exclude all nontestifying witnesses from the courtroom upon request to the judge.¹²⁵ Federal Rule 615 does create some exceptions,¹²⁶ but the only relevant one provides that the judge may allow a person to remain in the courtroom "whose presence is shown by a party to be essential to the

122. The Federal Judicial Center noted that these pretrial innovations appeared to be working well in its 1998 Report on the Vaccine Program. JOHNSON ET AL., *supra* note 94, at 25–39.

123. See *Geders v. United States*, 425 U.S. 80, 87 (1976) (discussing the sequestering of witnesses); Sarah Chapman Carter, *Exclusion of Justice: The Need for a Consistent Application of Witness Sequestration Under Federal Rule of Evidence 615*, 30 U. DAYTON L. REV. 63, 63–64 (2004).

124. *Opus 3 Ltd. v. Heritage Park, Inc.*, 91 F.3d 625, 628 (4th Cir. 1996) (*citing* 6 JOHN HENRY WIGMORE, EVIDENCE IN TRIALS AT COMMON LAW § 1838, (James H. Chadbourn ed., 1976)).

125. FED. R. EVID. 615.

126. *Id.*

presentation of the party's cause.”¹²⁷ The courts have read this exemption, and the other exemptions in Rule 615, quite narrowly and have found it insufficient that the expert witness a party sought to have remain in the courtroom was merely “desirable” or “helpful”; the standard is a much higher one of the witness’s continued presence in the courtroom being “essential,” in that counsel would be unable to function effectively without the presence of the expert witness in court.¹²⁸

In vaccine cases, by contrast, the expert witnesses are not sequestered until they testify, but generally sit at counsel table throughout the entire proceeding, including all of the opening discussions, the testimony, and the legal arguments of the lawyers. They even consult with counsel during the proceeding. The experts can testify after having heard all prior fact testimony, and do not have to give their opinions based upon hypothetical facts or facts related to them from prior testimony. Not only do the experts in vaccine hearings have the opportunity to consult with counsel for their side during the entire hearing, but the special master may also grant requests for one expert to ask questions of the other side’s expert who is currently testifying on the witness stand. A special master can even allow the experts to have a dialogue between themselves on the record.

This modified procedure has a number of advantages. Knowing that each side’s expert is listening to the other’s every word encourages the experts to avoid more extreme or unsupportable claims. It also provides opportunities to ask the experts about what points they agree upon, which can substantially narrow the issues in dispute between the experts. The experts can also point out the problems they see with the other experts’ expressed views. This procedure encourages a more informed and less attorney-controlled decisionmaking process.

2. Front-Loading of Documents and Evidence

Congress imposed a front-loading requirement, which in theory requires that all petitions for compensation be accompanied by complete documentation, including all medical records (which for a young child would include prenatal, birth, and pediatric records) and affidavits or

127. *Id.*

128. *United States v. Klaphake*, 64 F.3d 435, 437 (8th Cir. 1995); *United States v. Agnes*, 753 F.2d 293, 307 (3d Cir. 1985). It would seem difficult for either counsel in a typical vaccine injury case to claim that the presence of an expert witness at counsel table was “essential” because these counsel are typically very experienced and knowledgeable about vaccine injury litigation, and they could function effectively at the hearing even if their expert witnesses were not present at counsel table. Moreover, experts routinely submit their reports prior to hearing, and these are routinely shared and discussed by counsel and counsel’s expert witnesses.

statements from all fact witnesses and expert witnesses that petitioner intends to rely on in the case.¹²⁹ The Secretary of HHS is also directed to respond to the petition for compensation with all objections and include all supporting medical documentation and expert opinions on which HHS seeks to rely.¹³⁰ Although these requirements have the desired effect of getting some potentially relevant information into the record at the earliest possible date, the typical case is usually burdened by substantial delays in completing the record. Hospitals or other healthcare providers delay or resist providing the needed documentation, and delays occur for other reasons as well. This procedure has certainly been an improvement over the “hide the ball” discovery that can be typical in civil cases, but it has not substantially expedited the cases. Reports issued by the GAO and the Federal Judicial Center have documented both the advantages of the front-loading procedure and the continuing problems with the delays in vaccine cases.¹³¹

3. Informal Procedures, Including Telephonic Conferences

There are a number of other informal and electronic pretrial procedures that the Vaccine Compensation Program has adopted to good effect. For example, shortly after the parties have submitted the petition and report, an informal, off-the-record status conference is generally held by telephone, during which the special master provides counsel with preliminary thoughts or ideas about the strengths and weaknesses of the case, and the parties can also talk informally about procedures for resolving the case.¹³² These conferences also identify omissions in the record, the need for additional testimony, and matters of timing that need to be addressed.

In the Vaccine Program, virtually all pretrial status conferences and other pretrial proceedings are conducted telephonically, with the special master’s office connecting counsel for both sides. Telephonic pretrial proceedings are much more efficient than the typical practice of bringing counsel and parties into a courtroom to wait while other cases are heard, resulting in attorneys wasting time and generating unnecessary fees.

The telephonic status conferences are a necessity in a court with nationwide jurisdiction, involving petitioners’ counsel and pro se petitioners located in all parts of the United States. However, the clear benefits in

129. 42 U.S.C. §§ 300aa-11(c) to (e) (2006). These records must be filed electronically. *See supra* note 47.

130. U.S. CT. OF FED. CLAIMS VACCINE R. 4(c).

131. GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 2–3, 5; JOHNSON ET AL., *supra* note 94, at 25–27.

132. U.S. CT. OF FED. CLAIMS VACCINE R. 5(a).

time, cost, and efficiency in holding routine status conferences and other pretrial proceedings telephonically should be experimented with by other courts regardless of geographical considerations. The usefulness of these procedures has been documented in several governmental reports on the Vaccine Compensation Program.¹³³

4. *Omnibus Proceedings*

Another creative solution invented by the Office of Special Masters to consider multiple cases raising similar vaccine injury issues is the “omnibus proceeding.” In these omnibus proceedings, multiple cases are consolidated for purposes of joint evidentiary hearings and decisions on general questions of causation. Sometimes omnibus proceedings are formed to unify decisions on specific test cases, and sometimes to apply new “Tables” of presumed vaccine injury causation that are issued by the special masters themselves.

The omnibus autism proceeding has been the largest and longest running omnibus proceeding, involving more than 5,000 individual petitioners.¹³⁴ It began in 2002, and is still ongoing in 2011.¹³⁵ It is also the omnibus proceeding that has generated the most controversy.¹³⁶ This

133. See GAO VACCINE COMPENSATION REPORT, *supra* note 95, at 2–3; JOHNSON ET AL., *supra* note 94, at 34–43, 44.

134. Snyder v. Sec'y of the Dep't of Health & Human Servs., No. 01-162V, 2009 WL 332044, at *4–5 n.12 (Fed. Cl. Feb. 12, 2009).

135. *Id.* at *4–7.

136. See generally Steven J. Meyers, Note, *Denying the Obvious: Why the Special Masters Should Have Found for Petitioners in the Autism Omnibus Test Cases*, 20 FED. CIR. B.J. 633 (2011). These controversies have included the excessive time it is taking to resolve the cases, the improper exclusion of evidence offered by petitioners, and the division of the omnibus proceeding between three special masters who heard the general causation evidence together in one consolidated hearing. See, e.g., Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d 1343, 1345 (Fed. Cir. 2010) (noting that the full record encompassed “tens of thousands of pages of medical literature, more than four thousand pages of hearing testimony, and fifty expert reports”); Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 721 (2009) (attempting to exclude expert reports because of the “last-minute” nature of the evidence); Joëlle Anne Moreno, *It's Just a Shot Away: MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1511, 1514–15 (2009) (discussing how Special Master George L. Hastings reviewed “23 separate medical expert reports, heard live testimony from 16 expert witnesses, and reviewed 658 medical journal articles” all on his own); Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 513 (2008) (recommending changes in the autism proceeding and the elimination of all omnibus proceedings); *Parents and Physicians Outraged Over Comments from NBC's Dr. Snyderman on Autism Omnibus Hearings*, BIOTECH Wk., July 4, 2007, available at 2007 WLNR 12218153; Jordan

complex proceeding is exploring several alternate links between vaccines and autistic spectrum disorders, and it is divided between three different special masters who are considering issues simultaneously.¹³⁷ The three special masters have issued their rulings in the test cases, finding no likely relationship between the measles, mumps, and rubella (MMR) vaccines or thimerosal and autistic spectrum disorders, and these cases have been affirmed on appeal to date.¹³⁸

In 1992–1993, an omnibus proceeding was held involving the rubella vaccine and arthritis-like conditions before Special Master George L. Hastings. After conducting extensive hearings, Special Master Hastings issued a final ruling in which he concluded that the evidence more likely than not showed that the rubella vaccine caused a chronic arthropathy if a number of specific conditions were satisfied.¹³⁹

Special Master Hastings in effect grafted a new Table for the rubella vaccine into the Vaccine Act. The criteria he established functioned exactly as did the criteria for other Table injuries—they created a

Weissmann, *Lawyers: Autism Rulings Won't End Litigation*, LAW.COM (Feb. 16, 2009), <http://www.law.com/jsp/article.jsp?id=1202428201092>.

137. The principal questions that have been litigated are whether the measles, mumps, and rubella (MMR) vaccines cause autism and whether the vaccine additive thimerosal causes autism.

138. Dwyer v. Sec'y of the Dep't of Health & Human Servs., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010) (Special Master Denise K. Vowell); King v. Sec'y of Health & Human Servs., No. 03-584V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010) (Special Master George L. Hastings); Mead v. Sec'y of Health & Human Servs., No. 03-215V, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010) (Special Master Patricia Campbell-Smith); Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009) (Special Master George L. Hastings), *aff'd*, 89 Fed. Cl. 158; Hazlehurst v. Sec'y of the Dep't of Health & Human Servs., No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009) (Special Master Patricia Campbell-Smith), *aff'd*, 88 Fed. Cl. 473, *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); Snyder v. Sec'y of the Dep't of Health & Human Servs., No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009) (Special Master Denise K. Vowell), *aff'd*, 88 Fed. Cl. 706 (2009). The cases decided to date have not rejected all possible links between vaccines and autism. For example, one autism case was recently settled where the vaccination significantly aggravated a pre-existing mitochondrial disorder. *See Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V, 2011 WL 678559 (Fed. Cl. Jan. 28, 2011) (judgment issued July 30, 2010).

139. These conditions were that: (1) the petitioner was at least eighteen years old when the vaccination was given, (2) the onset of the arthropathic symptoms occurred between one and six weeks after the vaccination, (3) petitioner developed an antibody response to the vaccine, (4) petitioner was free of polyarthropathy joint pain for at least three years prior to the vaccination, (5) there was no alternative explanation for the arthropathy, such as a diagnosis of rheumatoid arthritis, and (6) there was a continuation of symptoms for at least six months. *Ahern v. Sec'y of the Dep't of Health & Human Servs.*, No. 90-1435V, 1993 WL 179430, at *13 (Fed. Cl. Jan. 11, 1993).

rebuttable presumption that the rubella vaccine caused the injury, but this presumption could be overcome by a showing that some other condition was the actual cause of the symptoms. It is true, as Special Master Hastings indicated in his final decision,¹⁴⁰ that the criteria he established did not conclusively determine any future case that a petitioner might bring because a future petitioner was free to introduce additional evidence and argue for a different result. However, it is also true that any party in any case can always ask the decisionmaker to reconsider a previously taken position. Yet without providing dramatic new evidence, a petitioner is not likely to be successful.¹⁴¹

Another omnibus proceeding, held in 2006, involved whether the hepatitis B vaccine causes four demyelinating conditions: transverse myelitis (TM), chronic inflammatory demyelinating disease (CIDP), Guillain–Barre syndrome (GBS), and multiple sclerosis (MS). Special Master Laura D. Millman ruled in favor of the petitioners in each of the four paradigm cases¹⁴² and created a judicial scheme that operated almost as if it were a “Table” for the hepatitis B vaccine, with a presumption that the vaccine caused the conditions if the onset was between three and thirty days of the vaccination.¹⁴³ Other omnibus proceedings have involved improperly

140. *Id.* at *11.

141. Dramatic new evidence in the form of new studies did appear a few years later involving the rubella vaccine and arthropathy. This led the Department of Justice to ask Special Master Hastings to reopen the omnibus proceeding and, in light of the new studies, to throw out the prior standards he had established for presumed causation. *See Snyder*, 2002 WL 31965742, at *11. Special Master Hastings agreed to re-open the omnibus proceeding, held hearings on the newly published studies, and concluded that he should keep his prior criteria for entitlement with two minor modifications: (1) he broadened the requirement that the petitioner must be at least eighteen years of age to a requirement that the petitioner be past puberty, but (2) he narrowed the time period for the onset of the arthropathy from a one to six week period to a seven to twenty-one day period. *Id.* at *20.

142. *Werderitsh v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-310V, 2006 WL 1672884, at * 27 (Fed. Cl. May 26, 2006) (finding a connection between the vaccine and multiple sclerosis); *Peugh v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-638V, 2006 WL 5668229, at *13 (Fed. Cl. Apr. 21, 2006) (finding a connection between the vaccine and Guillain–Barre syndrome); *Gilbert v. Sec'y of the Dep't of Health & Human Servs.*, No. 04-455V, 2006 WL 1006612, at *12 (Fed. Cl. Mar. 30, 2006) (finding a connection between the vaccine and chronic inflammatory demyelinating disease); *Stevens v. Sec'y of the Dep't of Health & Human Servs.*, No. 99-594V, 2006 WL 659525, at *25 (Fed. Cl. Feb. 24, 2006) (finding a connection between the vaccine and transverse myelitis).

143. *Stevens*, 2006 WL 659525, at *12, *15. In a subsequent decision, based on new evidence, Special Master Millman extended the appropriate temporal relationship out to two months for TM. *Pecorella v. Sec'y of the Dep't of Health & Human Servs.*, No. 04-1781V, 2008 WL 4447607, at *5 (Fed. Cl. Sept. 17, 2008).

manufactured polio vaccines¹⁴⁴ and the relationship of the hepatitis B vaccine to type I diabetes.¹⁴⁵

These omnibus proceedings conducted by the special masters have been a creative and effective use of the program's resources, despite the fact that some of the proceedings have been controversial.¹⁴⁶ There is no explicit authority in the Vaccine Act for such omnibus proceedings, so the special masters have based their authority to hold such consolidated proceedings on the broad discretion and authority that the Act gives the special masters to structure and control proceedings in the Vaccine Compensation Program.¹⁴⁷ These omnibus proceedings are also the result of the major shift in the Vaccine Compensation Program to off-Table cases, so that the special masters are seeking in effect to create their own "Tables" to address some of the difficult off-Table injuries that commonly recur in the program.

II. OTHER RECENT FEDERAL COMPENSATION PROGRAMS

Subsequent to the adoption of the Vaccine Act, Congress enacted five other major federal compensation programs: the Radiation Exposure Compensation Program, the Japanese-American internment compensation program, the Smallpox Compensation Program, the September 11th Compensation Program, and the Countermeasures Compensation Program. These compensation programs were, like the Vaccine Act, often a blend of humanitarian, compassionate concerns for injured individuals, and a desire to protect industries that were too big or important to fail.

144. *Gherardi v. Sec'y of the Dep't of Health & Human Servs.*, No. 90-1466V, 1997 WL 53449, at *1 (Fed. Cl. Jan. 24, 1997); *Baggott v. Sec'y of the Dep't of Health & Human Servs.*, No. 90-2214V, 1992 WL 79987, at *1 (Cl. Ct. Apr. 2, 1992).

145. *Hennessy v. Sec'y of the Dep't of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053, at *2, *59 (Fed. Cl. May 29, 2009), *aff'd*, 91 Fed. Cl. 126, 142 (2010) (holding that there was no proven relationship between the hepatitis B vaccine and type I diabetes).

146. See *supra* note 136 and accompanying text. In both *Snyder* and *Cedillo*, the Court of Federal Claims judges ruled that it was not improper for the omnibus proceeding to be divided between three special masters who heard the evidence of general causation together in one consolidated hearing. The *Snyder* court said that this procedure "reflects a common-sense, cost-saving approach to complex litigation." *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 721 (2009). The *Cedillo* court called it "an eminently reasonable case management approach." *Cedillo v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 158, 174 (2009).

147. *Snyder*, 2009 WL 332044, at *2. Special Master Denise K. Vowell has noted that omnibus proceedings "bear some resemblance to multi-district litigation in federal district court." *Dwyer v. Sec'y of the Dep't of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *2 n.9 (Fed. Cl. Mar. 12, 2010). Omnibus proceedings also share similarities with administrative rulemaking proceedings and class action lawsuits. *Hazlehurst v. Sec'y of the Dep't of Health & Human Servs.*, No. 03-654V, 2009 WL 332306, at *2–3 (Fed. Cl. Feb. 12, 2009).

Additionally, there was a desire to promote other important national interests, including public health and national security interests. While each of these programs arose from unique circumstances, they share many similarities and some important differences.

Some of the features of these newer compensation programs, such as the relaxed burden of proof imposed on petitioners, should be adopted in the Vaccine Program. These newer programs also offer valuable lessons for compensation programs that Congress may consider adopting in the future. The background and key features of these newer compensation programs are briefly described below.¹⁴⁸

A. The Radiation Exposure Compensation Program

Congress passed the Radiation Exposure Compensation Act (RECA) in 1990.¹⁴⁹ The Act contained an apology and provided limited compensation to individuals who developed serious diseases as a result of exposure to radiation from above-ground atomic weapons testing, and to individuals who participated in the mining or transportation of radioactive materials used in making the nuclear devices.¹⁵⁰

RECA recognized, after many years of official government denials, that persons exposed to radiation in connection with the nuclear weapons production program “were subjected to [an] increased risk of injury and disease to serve the national security interests of the United States,”¹⁵¹ and that it was appropriate “to make partial restitution . . . for the burdens they

148. The descriptions of these five compensation programs must, out of space considerations, be necessarily brief. For similar space reasons, it is not possible to discuss, in this Article, other earlier federal compensation programs, such as the 1969 Black Lung Compensation Plan, 30 U.S.C. § 901–944 (2006), or other federal programs that pay disability benefits to military veterans, law enforcement officers, and a variety of other groups. This Article does not discuss the swine flu vaccination program in 1976–1977. See RICHARD E. NEUSTADT & HARVEY L. FINEBERG, THE EPIDEMIC THAT NEVER WAS (1983). International compensation laws are also outside the scope of this Article. See, e.g., Rob Henson, Comment, *Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Great Britain*, 15 TULSA J. COMP. & INT'L L. 61 (2007) (discussing the vaccination compensation program of Great Britain).

149. Radiation Exposure Compensation Act, Pub. L. No. 101-426, 104 Stat. 920 (1990) (codified as amended at 42 U.S.C. § 2210 note (2006) (Radiation Exposure Compensation)).

150. The Department of Justice reports that, as of September 22, 2011, a total of 24,468 claims for compensation have been approved, 9,492 have been denied, and 467 claims are currently pending. CIVIL DIV., U.S. DEP’T OF JUSTICE, RADIATION EXPOSURE COMPENSATION SYSTEM: CLAIMS TO DATE SUMMARY OF CLAIMS RECEIVED BY 09/22/2011 (2011), http://www.justice.gov/civil/omp/omi/Tre_SysClaimsToDateSum.pdf. A total of \$1,620,884,889 has been paid out. *Id.*

151. 42 U.S.C. § 2210 note (Radiation Exposure Compensation § 2(a)(5)).

have borne for the nation as a whole.”¹⁵² As in the Vaccine Act, RECA created a “Table” of eligible individuals who could collect compensation if they could establish that they suffered a specified illness within a specified timeframe.¹⁵³ Petitioners were required to submit documentation showing that they satisfied the eligibility criteria in the Act.¹⁵⁴ However, RECA also contained a provision that “all reasonable doubt with regard to whether a claim meets the requirements of this Act shall be resolved in favor of the claimant.”¹⁵⁵

RECA created a largely inquisitorial procedure for resolution of the radiation injury claims. The petition for compensation was filed with, and reviewed by, officials in the Civil Division of the Department of Justice.¹⁵⁶ The claim was evaluated by a claims examiner, by an attorney, and then by the assistant director of the Civil Division, before a final decision was made.¹⁵⁷ Petitioners who were denied compensation could either file an appeal in court or refile their claim up to three times with the Department

152. *Id.* § 2210 note (§ 2(b)). The U.S. Government Accountability Office explained in a report on the program:

From 1945 through 1962, the United States conducted a series of aboveground atomic weapons tests as it built up its Cold War nuclear arsenal. Around this same time period, the United States also conducted underground uranium-mining operations and related activities, which were critical to the production of the atomic weapons. Many people were exposed to radiation resulting from the nuclear weapons development and testing program, and such exposure is presumed to have produced an increased incidence of certain serious diseases, including various types of cancer.

U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-1037R, RADIATION EXPOSURE COMPENSATION ACT: PROGRAM STATUS 1 (2007) [hereinafter GAO RADIATION EXPOSURE ACT REPORT].

153. The Radiation Exposure Compensation Act (RECA) created three classes of individuals who were eligible for compensation. First, “unwitting participants” who resided in certain areas of Utah, Nevada, and Arizona, who had been exposed to radiation as a result of their proximity to above-ground nuclear testing and who developed specified diseases (including leukemia and a number of forms of cancer) within five years of their first exposure to the radiation, were entitled to receive a one-time lump-sum payment of \$50,000. 42 U.S.C. § 2210 note (Radiation Exposure Compensation § 4(a)(1)(B)(i)). Second, “onsite participants” in the testing program who developed the same specified diseases within five years of their first exposure to the radiation were entitled to receive a lump sum payment of \$75,000. *Id.* § 2210 note (§ 4(a)(1)(B)(ii), (a)(2)(C)). Third, individuals who were employed for at least one year in uranium mining, milling, or transportation, or who were exposed to forty or more “working level months of radiation,” and who subsequently developed specified diseases (including lung and renal cancers, respiratory disease, or other chronic renal diseases) within the applicable time period, were entitled to receive a lump sum payment of \$100,000. *Id.* § 2210 note (§ 5(a)(1)).

154. *Id.* § 2210 note (§§ 4(a)(2)(C), 5(a)(1)(A)(ii)(I)-(II)).

155. *Id.* § 2210 note (§ 6(b)(1)).

156. *Id.*

157. GAO RADIATION EXPOSURE ACT REPORT, *supra* note 152, at 15.

of Justice to try to correct an alleged deficiency that was the basis for the denial of the claim.¹⁵⁸ RECA allows petitioners to be represented by lawyers, who are authorized to charge a small contingency fee for successful claims.¹⁵⁹

RECA has been criticized on a number of grounds. The GAO expressed concern that claims were often being resolved outside of the RECA-mandated twelve-month period of time.¹⁶⁰ The GAO also noted that the program's efforts to assist potential petitioners with the application process were uneven at best.¹⁶¹ Inadequate assistance was a particular concern in cases involving older people suffering from cancers or other serious health problems who needed substantial and compassionate assistance in providing the detailed information and compiling the documentation necessary to demonstrate eligibility for compensation. The program has also been criticized for its failure to "fully compensate" or "fully apologize" to injured persons,¹⁶² and for its "'burdensome' procedures" and "'excessive regulatory hurdles.'"¹⁶³ Congress has taken

158. *Id.* at 16. Petitioners could also refile if they believed that they became eligible for compensation as a result of regulatory changes adopted by the Department of Justice in 1999 or because of an amendment to the Act in 2000. *Id.*

159. 42 U.S.C. § 2210 note (Radiation Exposure Compensation § 9); 28 C.F.R. § 79.74(a)–(b) (2010). The percentage varies from under two percent to up to ten percent depending on the type of case. *Id.* § 79.74(b).

160. According to the Government Accountability Office (GAO), only 89% of claims have been resolved within the required time period. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-01-1043, RADIATION EXPOSURE COMPENSATION: ANALYSIS OF JUSTICE'S PROGRAM ADMINISTRATION 2 (2001) [hereinafter GAO RADIATION COMPENSATION ANALYSIS].

161. The GAO contacted eleven nongovernmental organizations involved in RECA-related activities, including radiation survivor groups and Native American assistance groups. *Id.* at 22. Of the organizations, six of the eleven organizations believed that the Radiation Exposure Compensation Program (RECP) "was of little to no help in explaining the requirements for documentation to substantiate applicant claims, but five believed that RECP was generally to very helpful." *Id.* at 23.

162. Jessica Barkas Threet, *Testing the Bomb: Disparate Impacts on Indigenous Peoples in the American West, the Marshall Islands, and in Kazakhstan*, 13 U. BALT.J. ENVTL. L. 29, 50 (2005).

163. A. COSTANDINA TITUS, BOMBS IN THE BACKYARD: ATOMIC TESTING AND AMERICAN POLITICS 149 (2d ed. 2001). The relatively low lump-sum payments given in the program

did little to assuage grief, placate anger, mete out justice, or restore a community's faith in Washington. As one reporter summarized the views of the downwinders, the money was "too little, too late, and too grudgingly given to fill the void left in their lives by the deaths of parents and children whose only sin was to be in the wrong place at the wrong time."

Id. at 149 (citation omitted).

some action to address these concerns.¹⁶⁴

B. *The Japanese-American Internment Compensation Program*

In 1942, President Franklin D. Roosevelt signed an executive order directing the Secretary of War to designate military areas for the internment of American citizens and residents of Japanese ancestry.¹⁶⁵ More than 120,000 Japanese-Americans, 70% of whom were U.S. citizens, were forced into these camps until the end of World War II, suffering the loss of liberty, economic losses, and the stigma of suspected disloyalty.¹⁶⁶ In 1988, Congress passed a compensation law that authorized the payment of \$20,000, and a letter of apology, to persons of Japanese ancestry, or surviving family members, who were interned in camps in the United States shortly after the attack on Pearl Harbor.¹⁶⁷

The Japanese-American internment compensation program involved an essentially inquisitorial procedure within the Department of Justice. The Attorney General, through the Office of Redress Administration, was directed to "identify and locate" all potentially eligible individuals and to notify them of their right to apply to the program.¹⁶⁸ Each was also to be

164. In 2000, Congress passed a compensation law that provided additional benefits to be paid to certain workers who had previously been found eligible to receive compensation under RECA. Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Pub. L. No. 106-398, § 3611, 114 Stat. 1654A-1, 1654A-497 to 513 (codified as amended at 42 U.S.C. § 7384d to 7385s-15). This Act also created the Energy Employees Occupational Illness Compensation Program for Department of Energy employees involved in the production of nuclear weapons. 42 U.S.C. § 7384(d). With respect to petitioner's burden of proof in this program, in most instances, the petitioner had the ordinary preponderance burden, but for injuries involving certain cancers, petitioners need only show that "the cancer was at least as likely as not" caused by the occupational exposure. 20 C.F.R. § 30.210(b)(1) (2010). For an overview and critique of this program, see generally U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-302, ENERGY EMPLOYEES COMPENSATION: ADDITIONAL INDEPENDENT OVERSIGHT AND TRANSPARENCY WOULD IMPROVE PROGRAM'S CREDIBILITY (2010).

165. Exec. Order No. 9066, 3 C.F.R. 1092–93 (1943).

166. Peter G. Chronis, *Infamous Relocation Recalled: Japanese-Americans Remember the Pain*, DENVER POST, Aug. 11, 1998, at B1. The U.S. Supreme Court upheld the constitutionality of the internments in *Korematsu v. United States*, 323 U.S. 214 (1944). In 1948, Congress authorized a limited reimbursement for property losses suffered as a result of the internment. Act of July 2, 1948, Pub. L. No. 80-886, 62 Stat. 1231.

167. Civil Liberties Act of 1988, Pub. L. No. 100-383, 102 Stat. 904 (1988) (codified at 50 U.S.C. app. §§ 1989a to 1989b-9 (2006)).

168. 50 U.S.C. app. § 1989b-4.

sent a letter from the President apologizing on behalf of the U.S. government for the internment actions.¹⁶⁹

Under the program, a petitioner files an application for compensation with the Office of Redress Administration, which makes a determination as to the claimant's eligibility.¹⁷⁰ If the petitioner was found ineligible, the petitioner could seek reconsideration from the Appellate Section of the Department of Justice's Civil Rights Division, and then judicial review in the U.S. Court of Federal Claims.¹⁷¹

As with the Radiation Compensation Law, the Japanese-American internment compensation law contained a "benefit of the doubt" provision mandating that compensation be awarded if there was "an approximate balance of positive and negative evidence" with respect to a claimant's eligibility.¹⁷² Also similar to the Radiation Compensation Law, the Japanese-American internment compensation law provided substantial, but only partial, monetary compensation, together with an apology from the U.S. government for its actions. Another important, more intangible, objective of the Japanese-American internment compensation law was the educational purpose of informing the American people of the injustices involved in the internment program.¹⁷³

169. See 50 U.S.C. app. § 1989 (offering Presidential pardons to persons who were recommended by the Attorney General).

170. 50 U.S.C. app. § 1989b-4(a). In this program, 82,219 individuals were found to satisfy the requirements for compensation. *Japanese Americans: Check for Compensation and Reparations for the Evacuation, Relocation, and Internment*, NAT'L ARCHIVES, <http://archives.gov/research/japanese-americans/redress.html> (last visited Sept. 24, 2011). The total amount of compensation paid was approximately \$1.6 billion. *Id.* It was initially estimated that about 60,000 claims would be paid from the fund, and this underestimation was based upon the mistaken use of actuarial tables containing the life expectancies of Caucasian males. ALICE YANG MURRAY, HISTORICAL MEMORIES OF THE JAPANESE AMERICAN INTERNMENT AND THE STRUGGLE FOR REDRESS 352 (2008).

171. 50 U.S.C. app. § 1989b-4(h). The Act imposed no limitations on a claimant's ability to be represented by, or to compensate, an attorney.

172. Section 1989b-4(a)(3) provides:

(3) Benefit of the doubt

When, after consideration of all evidence and relevant material for determining whether an individual is eligible individual, there is an approximate balance of positive and negative evidence regarding the merits of an issue material to the determination of eligibility, the benefit of the doubt in resolving each such issue shall be given to such individual.

50 U.S.C. app. § 1989b-4(a)(3). This provision was not included in the compensation law as originally passed, but was added by an amendment in 1992. Civil Liberties Act Amendments of 1992, Pub. L. No. 102-371, § 4(a), 106 Stat. 1167, 1167.

173. MITCHELL T. MAKI, HARRY H.L. KITANO & S. MEGAN BERTHOLD, ACHIEVING THE IMPOSSIBLE DREAM: HOW JAPANESE AMERICANS OBTAINED REDRESS 225 (1999). The advocates of the Act saw the publicity generated by its introduction and passage as having

The battle for the compensation fund was led on Capitol Hill by Representatives Robert T. Matsui and Norman T. Mineta, two well respected and influential men of Japanese-American ancestry who had both been in the camps as young children.¹⁷⁴ Also influential were two Japanese-American Senators, Dan Inouye and Spark Matsunaga, both of whom had been war heroes in World War II.¹⁷⁵ The Japanese American Citizens League, and other community groups, also pressed for this legislation.¹⁷⁶

One scholar has concluded that this compensation program was successful because it was cathartic for many Japanese-Americans, because it restored a measure of dignity lost through the internment, and because the government's apology and the symbolic reparations payment fostered long-overdue healing in the Japanese-American community.¹⁷⁷ Another scholar has described this compensation law, and others like it, as "primarily symbolic," bringing a sense of closure.¹⁷⁸

an important educational value. *See, e.g.*, Robert L. Koenig, *Internment Bill Is Meant to "Admit, Redress Wrongs."* ST. LOUIS POST-DISPATCH, May 1, 1988, at 1A; *A National Apology*, TIME, Oct. 22, 1990, at 35. Funding was also provided for a permanent museum exhibition in Washington, D.C., to tell the story of the internment and the compensation law. Eric K. Yamamoto & Ashley Kaiao Obrey, *Reframing Redress: A "Social Healing Through Justice" Approach to United States–Native Hawaiian and Japan–Ainu Reconciliation Initiatives*, 16 ASIAN AM. L.J. 5, 18 (2009).

174. Koenig, *supra* note 173.

175. LESLIE T. HATAMIYA, *RIGHTING A WRONG: JAPANESE AMERICANS AND THE PASSAGE OF THE CIVIL LIBERTIES ACT OF 1988* 111–13 (1993). This book also contains a detailed history of the Act's passage. *Id.* at 111–28.

176. *Id.* at 113–16. The different Japanese-American groups had different perspectives on the meaning of the internment and on the appropriate redress for it. MURRAY, *supra* note 170, at 3. The \$20,000 amount reflected a political compromise between those who were concerned that too low a figure would make the financial payment seem like a mere token amount, and those who thought too high a figure would make passing the compensation bill impossible. *Id.* at 353.

177. Eric K. Yamamoto, *Racial Reparations: Japanese American Redress and African American Claims*, 40 B.C. L. Rev. 477, 477–78 (1998). Professor Yamamoto quoted one former internee who said that "although monetary payments 'could not begin to compensate . . . for his . . . lost freedom, property, livelihood, or the stigma of disloyalty,' the reparations demonstrated the sincerity of the government's apology." *Id.* at 518 (alteration in original) (quoting NICHOLAS TAVUCHIS, *MEA CULPA: A SOCIOLOGY OF APOLOGY AND RECONCILIATION* 107 (1991)).

178. GREG ROBINSON, *A TRAGEDY OF DEMOCRACY: JAPANESE CONFINEMENT IN NORTH AMERICA* 302 (2009).

C. The Smallpox Compensation Program

President George W. Bush, concerned that the nation was vulnerable to a bioterrorism attack using the smallpox virus, announced his plan for a nationwide civilian smallpox vaccination program on December 13, 2002.¹⁷⁹ President Bush's vaccination plan did not initially include any provision for compensating those injured by the vaccinations. At the end of January 2003, the Secretary of HHS, Tommy G. Thompson, promised that in Phase I of the plan 500,000 healthcare providers and other emergency responders would volunteer to be vaccinated within a month. However, when that one-month mark was reached, only 4,200 people—less than one percent of the promised amount—had agreed to be vaccinated.¹⁸⁰

An important reason for such an abysmal start to the smallpox immunization program appeared to be the lack of a plan to create a safety net for those injured by the smallpox vaccine, either by receiving it themselves or by coming into contact with someone who had recently been vaccinated.¹⁸¹ The Bush Administration had suggested that, even without a federal compensation program, persons injured by the smallpox vaccinations could seek compensation through other avenues, but these other avenues for relief were speculative at best.¹⁸² Moreover, the

179. Suzanne Malveaux, *Bush Gets Smallpox Vaccine*, CNN.COM (Dec. 21, 2002, 10:13 PM), <http://archives.cnn.com/2002/US/12/21/bush.smallpox/index.html>.

180. See Ceci Connolly, *Bush Smallpox Inoculation Plan Near Standstill*, WASH. POST, Feb. 24, 2003, at A6 (noting that the intent of the program was to initially inoculate 500,000 frontline emergency response personnel, such as doctors, nurses, police officers, and firefighters, who would volunteer to participate in the vaccination program).

181. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-578, SMALLPOX VACCINATION: IMPLEMENTATION OF NATIONAL PROGRAM FACES CHALLENGES 4–5 (2003). In addition to a lack of an adequate compensation program, other factors that likely contributed to the failure of the smallpox program include difficulties in getting the smallpox vaccine doses to the appropriate authorities, the speculative and uncertain nature of smallpox threat to America, and overextended public health and hospital resources. Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 8 (2005).

182. Among the suggested possibilities was seeking compensation under the Homeland Security Act of 2002, but this Act only provided compensation if the injury was the result of negligent conduct. Since the real concern was with the inherent dangerousness of the vaccine, and not its negligent administration, this provision afforded “little likelihood” of recovery. Greenberger, *supra* note 181, at 17–18. Another possibility for recovery suggested by the Bush Administration was under state workers’ compensation laws, but this was problematic for a number of reasons, including the fact that the inoculations were not mandated as part of the job but had instead been volunteered for by the emergency personnel. *Id.* at 19. Another questionable suggested alternative was compensation under private health insurance policies, but such policies might not have covered smallpox injuries, and would never have included compensation for lost income or pain and suffering. *Id.*

healthcare providers who were to be vaccinated in Phase I of the program were well aware that the smallpox vaccine is generally considered the most dangerous vaccine available today.¹⁸³

The combination of possible serious adverse health effects from the smallpox vaccine, the unclear risk of a bioterrorism attack using smallpox, and the lack of a compensation plan for those injured, “dealt the smallpox campaign a near-death blow.”¹⁸⁴ Hundreds of major hospitals, several statewide nurses’ associations, and the health departments in several states refused to participate in the program.¹⁸⁵ A number of other organizations, including the AFL-CIO, the American Hospital Association, the American Nurses Association, and the American Public Health Association, expressed concerns about participation in the smallpox program until the liability compensation issues were resolved.¹⁸⁶

In an effort to resuscitate its smallpox program, the Bush Administration finally supported, and Congress adopted in late 2003, a compensation program for persons injured as a result of the program. The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA)¹⁸⁷ created a limited compensation program for the emergency responders injured by the smallpox vaccination, as well as for persons who suffered injuries as a result of having come into contact with the emergency responders who had been

183. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, described the current live virus smallpox vaccine as the “least safe human vaccine” available today. Susan J. Landers, *Smallpox Vaccine Hazards Dictate Cautious Approach*, AMEDNEWS.COM (Aug. 19, 2002), <http://www.ama-assn.org/amednews/2002/08/19/hlsb0819.htm>; *see also* Rutkow et al., *supra* note 10, at 725 (stating that the smallpox vaccine carries significant health risks). The Centers for Disease Control and Prevention has estimated that one person out of every 1,000 vaccinated would experience a serious adverse reaction, and that one to two persons out of 1,000,000 vaccinated with the smallpox vaccine would die as a result of it. CTRS. FOR DISEASE CONTROL & PREVENTION, SMALLPOX FACT SHEET 2 (2003), <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/vaccine-overview.pdf>.

184. Cynthia P. Schneider & Michael D. McDonald, “*The King of Terrors*” Revisited: *The Smallpox Vaccination Campaign and Its Lessons for Biopreparedness*, 31 J.L. MED. & ETHICS 580, 583 (2003).

185. *See id.* (noting that hospitals and states suspended the program because of possible adverse effects stemming from the vaccination).

186. Elin Gursky & Avani Parikh, *Some Right Jabs and Back in the Ring: Lessons Learned from the Phase I Civilian Smallpox Program*, 8 J. HEALTH CARE L. & POL’Y 162, 174–75, 175 nn.105 & 107–108 (2005).

187. Pub. L. No. 108-20, 117 Stat. 638 (2003) (codified at 42 U.S.C. §§ 239–239h (2006)).

vaccinated, such as hospital patients or family members of the emergency responder.¹⁸⁸

SEPPA, and its implementing HHS regulations, created a Smallpox Vaccine Injury Table containing a list of injuries and the specified interval for the first manifestation of those injuries.¹⁸⁹ Under SEPPA, the petitioner had the burden of proving by a preponderance of the evidence that the Table requirements were satisfied. If this burden was satisfied, then a presumption was created that the smallpox vaccine caused the injury.¹⁹⁰ The burden then shifted to the Secretary of HHS to show that something other than the smallpox vaccine actually caused the injury.¹⁹¹ If the injury suffered was not listed on the Table, or occurred outside of the timeframe specified in the Table, then the petitioner had the burden of proving by a preponderance of the evidence that the vaccine in fact caused the injury.¹⁹²

188. A total of sixty-three requests for compensation were filed under the Smallpox Compensation Program as of November 29, 2007. Some fifteen people had been determined to be eligible for compensation, sixteen requests were denied because they were filed too late, twenty-one requests were denied because no supporting medical records had been submitted or the medical records submitted were insufficient to support the claim, and six other claims were denied for other reasons or withdrawn. These statistics were provided to this Author in response to a Freedom of Information Act request filed with the Smallpox Vaccine Program. Letter from Mona Finch, Freedom of Info. Officer, Dep't of Health & Human Servs. to Peter H. Meyers, Professor, The George Wash. Univ. Law Sch. (Nov. 29, 2007) (on file with Author).

189. 42 C.F.R. § 102.21(a) (2010).

190. 42 U.S.C. § 239a(c) (2006).

191. *See id.*

192. 42 C.F.R. § 102.20(d).

For those persons who could establish entitlement to compensation, SEPPA provided less than total compensation for the injuries incurred:

- No compensation for pain and suffering was authorized in the statute.
- Lost income could be recovered, but it would not be 100 percent of the injured person's lost income, but only a prorated amount.¹⁹³
- No lost income would be paid if the claimant missed five days of work or less.¹⁹⁴
- A cap was placed on lost income that allowed no more than \$50,000 to be paid in any year.¹⁹⁵
- Although death benefits could be awarded under the statute, no more than \$50,000 in death benefits could be paid to the claimant's beneficiaries in any year.¹⁹⁶

SEPPA contained several other provisions that also raised substantial difficulties for potential petitioners. The statute of limitations required vaccine recipients to file their claim within one year of the administration of the smallpox vaccine.¹⁹⁷ For persons who suffered injuries as a result of contact with the vaccinated individual, the statute of limitations was two years.¹⁹⁸ The regulations explicitly provided that no judicial review was available from a decision refusing to award compensation.¹⁹⁹ No time limitation was placed on the Secretary of HHS for ruling on pending applications for compensation.²⁰⁰

The proceeding at HHS was purely inquisitorial, and it was conducted without any active participation by the petitioner. Moreover, the Secretary was authorized to consult with medical experts in making determinations of eligibility, without offering the petitioner an opportunity to respond.²⁰¹ If the Secretary denied compensation, the only recourse for the claimant was to file a request for reconsideration within sixty days.²⁰² The request for

193. If the injured petitioner had no dependents at the time that the injury occurred, the petitioner would receive 66.6% of his or her lost gross income, and if the petitioner did have dependents, then the petitioner could receive 75% of his or her lost income. *Id.* § 102.81(a)(1)(i)–(ii).

194. *Id.* § 102.81(c)(3).

195. *Id.* § 102.81(c)(1).

196. *Id.* § 102.82(d)(2)(i).

197. *Id.* § 102.42(c).

198. *Id.* § 102.42(d).

199. *Id.* § 102.92.

200. The Secretary of HHS was directed to "make the decision in a timely manner," but there were no standards or timeframes elucidating what a "timely manner" meant. *Id.* § 102.70(c).

201. *Id.* § 102.20(a).

202. *Id.* § 102.90(a).

reconsideration could not include or make reference to any additional information not included in the initial petition for compensation.²⁰³ A final decision was then made by the Associate Administrator and no further administrative review was allowed unless the President specifically directed otherwise; as noted above, no judicial review was authorized.²⁰⁴ HHS regulations allowed petitioners to be represented by a lawyer or a nonlawyer, but it did not authorize for payment of attorneys' fees and costs.²⁰⁵

Not surprisingly, given the limited compensation and the inhospitable procedures contained in SEPPA, the new law was unable to resuscitate the Smallpox Vaccination Program. SEPPA's compensation regime was simply too little, too late.²⁰⁶ On October 15, 2003, the Director of Smallpox Preparedness and Response at the Centers for Disease Control announced that the program was effectively over: "The fact is, it's ceased . . . not that anyone's issued an edict to say stop."²⁰⁷ In fact, over the entire life of the smallpox vaccination program, fewer than 40,000 emergency responders ever volunteered to be vaccinated, which was less than ten percent of the 500,000 people that HHS promised would be vaccinated within the first month of the program.²⁰⁸ In sum, the smallpox vaccination program was a resounding failure, and a major reason for that failure was the perception that it lacked an adequate compensation plan to protect individuals who might be injured by the vaccination.²⁰⁹

203. *Id.*

204. *Id.* § 102.90(c), .92.

205. *Id.* § 102.44(a), (d).

206. Greenberger, *supra* note 181, at 21.

207. Anita Manning, *Smallpox Vaccination Plan "Ceased"; Program is Cog of Bioterror Response*, USA TODAY, Oct. 16, 2003, at A1.

208. *Smallpox Vaccination Program Status by State*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/media/pressrel/smallpox/spvaccin.htm> (last updated Oct. 31, 2011).

209. Greenberger, *supra* note 181 at 8; Gursky & Parikh, *supra* note 186, at 176. Gursky and Parikh concluded:

Among the most regrettable "losses" [from the smallpox program] was a loss of trust, a phenomenon that occurred across multiple levels. Hospitals, clinicians, professional organizations, labor unions, and potential vaccines expected that their sacrifices of time and the potential risk to self and others would be met with appropriate levels of legal protections. In fact . . . inadequate regimes of liability and compensation eroded—early on—attempts to vaccinate anywhere near the intended number of 500,000 civilian emergency responders.

Id. at 184.

D. The September 11th Compensation Program

Congress passed the September 11th Victim Compensation Fund just eleven days after the attacks on the Twin Towers in New York City and on the Pentagon outside of Washington, D.C., in 2001.²¹⁰ The fund was established in part for compassionate reasons, to help those who were injured or who had a family member die as part of the September 11th attacks.²¹¹ Congress also made clear, however, that the most important objective of the Act was “to protect the airline industry, the World Trade Center’s owners and others from protracted, uncertain litigation.”²¹² Indeed, the very name of the omnibus legislation that created the September 11th Compensation Fund was the Air Transportation Safety and System Stabilization Act (ATSSSA).²¹³ There also appear to have been other very important intangible objectives for the program, reflecting important but difficult to quantify societal values. As Kenneth R. Feinberg, the September 11th Compensation Fund’s Administrator, wrote about the passage of the September 11th Compensation Fund:

Lawmakers . . . also wanted to show the world that, in the face of such an unprecedented attack, the American people would rally around the victims. Like the Marshall Plan that rescued Europe after World War II, the 9/11 Fund was a demonstration of American resolve in the wake of tragedy. The Nation would stand as one.²¹⁴

To be eligible for compensation under the September 11th Fund, the individual had to have been “present at the site” of one of the four airplane

210. September 11th Victim Compensation Fund of 2001, Pub. L. No. 107-42, 115 Stat. 237 (2001) (codified as amended at 49 U.S.C. § 40101 note (2006) (Air Transportation Safety and System Stabilization)).

211. Gillian K. Hadfield, *Framing the Choice Between Cash and the Courthouse: Experiences with the 9/11 Victim Compensation Fund*, 42 LAW & SOC’Y REV. 645, 649 (2008); see also Robert M. Ackerman, *The September 11th Victim Compensation Fund: An Effective Administrative Response to National Tragedy*, 10 HARV. NEGOT. L. REV. 135, 159–60 (2005) (noting, however, that the Victim Compensation Fund must be seen as a component of a larger measure to protect the airline industry).

212. Kenneth R. Feinberg, *9/11 Fund: Once Was Enough*, WASH. POST, Sept. 11, 2008, at A17. The Act was initially conceived as an emergency response to the crisis in the airline industry. The immediate problem was that “airline carriers, initially grounded for safety reasons, would stay on the ground indefinitely because their insurers would refuse to continue their coverage and capital markets would refuse to provide funds to the airlines in the face of potentially ‘unlimited’ liability.” Hadfield, *supra* note 211, at 649.

213. 49 U.S.C. § 40101 note (Air Transportation Safety and System Stabilization Act § 101(1)). The Act took other steps to address the financial problems facing the airlines, including a limit on the liability of the air carriers for all claims arising from the September 11th attacks to \$1.5 billion for each airplane. Hadfield, *supra* note 211, at 649.

214. Feinberg, *supra* note 212.

crashes and “physically harmed” as a result of the crashes, or be the appropriate representative of such person.²¹⁵ These eligible persons had to make a choice of seeking compensation from the fund or filing a civil suit for damages.²¹⁶ This was an “either/or” choice, in contrast to the Vaccine Act’s staggered requirement of going to the Court of Federal Claims first, then having the option of rejecting the decision issued by that court and filing a civil action in state or federal court. Once a petitioner decided to go into the September 11th Fund, the petitioner was bound by the final decision of the special master.²¹⁷

The Act established a special master, appointed by the Attorney General, who was given very broad authority to authorize and pay compensation in appropriate cases. ATSSSA provided few specifics as to how the special master, or the September 11th compensation program, would operate.²¹⁸ For example, the Act did not set forth specific amounts of compensation to award to different petitioners for injury or death claims, although it did provide that payment should be made for both economic and noneconomic losses.²¹⁹ Both types of injuries were broadly defined in the Act.²²⁰

215. 49 U.S.C. § 40101 note (Air Transportation Safety and System Stabilization Act § 405(c)(2)(A)–(B)).

216. *Id.* § 40101 note (§ 405(c)(3)(B)(i)).

217. *See id.* (noting that upon submission of a claim an applicant would waive the right to file a civil action).

218. *Id.* § 40101 note (§ 404).

219. Special Master Feinberg developed a grid of presumed economic loss for decedents based on lost earnings or economic opportunities, age, and other information. *See KENNETH R. FEINBERG, FINAL REPORT OF THE SPECIAL MASTER FOR THE SEPTEMBER 11TH VICTIM COMPENSATION FUND OF 2001, VOL. 1*, at 7 (2004). The program’s regulations established a presumption of noneconomic losses for death at \$250,000 plus \$100,000 for any spouse and for each dependent. 28 C.F.R. § 104.44 (2010). Petitioners could seek to obtain more than the presumed amount by showing “extraordinary needs or circumstances” in their individual case. FEINBERG, *supra*, at 8. For September 11th survivors, the \$250,000 presumed noneconomic injuries could also be adjusted depending of the gravity of the injuries. 28 C.F.R. §§ 104.45–46.

220. Economic awards for physically injured victims consist primarily of “actual income or expenses incurred as a direct result of the injury and future lost income and costs caused by the future effects of the injury.” 49 U.S.C. § 40101 note (Air Transportation Safety and System Stabilization Act § 402(7)). The economic award also includes, in appropriate cases, “the value of household services the victim provided to the household.” *Id.* Compensable noneconomic losses were defined in very broad manner, to include:

[L]osses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic services), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

The Act required the special master to issue a final decision within 120 days of the filing of the claim, and it provided for no administrative or judicial review of the special master's decisions. The special master was given extraordinary authority to fill in the procedures and standards to be applied in the Act, and also very broad and unreviewable authority to process individual claims under the Act. One author has described Special Master Feinberg as being "unilaterally responsible for filling in nearly every detail of the program."²²¹ Among the important details that Special Master Feinberg created were a number of Tables showing presumptive amounts of compensation for each category of economic or noneconomic injury. In special circumstances individual petitioners could seek increases over the presumed Table amounts.²²²

The September 11th program was designed to process claims in an informal, nonadversarial manner, with the special master playing a basically inquisitional role. The Final Report on the program states that all hearings involving either entitlement or the amount of compensation to be awarded "were designed to be non-adversarial."²²³ Any testimony received at the hearing was required to be under oath, but there was no right of cross-examination.²²⁴ Fund officials worked with various federal government agencies in verifying and gathering necessary information to process a claim.²²⁵ Petitioners had the right to be represented by an attorney, and the Act had no restrictions on payment of attorney's fees.²²⁶

One author has challenged the view that the September 11th Fund was nonadversarial, noting that since no government lawyer was present to

Id. § 40101 note 402(9).

221. Elizabeth Berkowitz, *The Problematic Role of the Special Master: Undermining the Legitimacy of the September 11th Victim Compensation Fund*, 24 YALE L. & POL'Y REV. 1, 2 (2006).

222. See FEINBERG, *supra* note 219, at 8.

223. *Id.* at 10. A total of 3,962 hearings were held for 3,629 claims, and the majority of hearings—3,044—were regarding the calculation of the award. *Id.* at 18. The Air Transportation Safety and System Stabilization Act (ATSSSA) gives petitioners the right to have an attorney represent them and the right to present appropriate witnesses and documents at the hearing, including expert witnesses where appropriate. 49 U.S.C. § 40101 note (Air Transportation Safety and System Stabilization Act § 405(b)(4)); September 11th Victim Compensation Fund of 2001, 66 Fed. Reg. 66,274, 66,280 (Dec. 21, 2001) (interim final rule). Special Master Feinberg initially indicated that hearings would generally not proceed for longer than two hours, but subsequently clarified in the Final Rule that there were "no firm time limit[s] for hearings." September 11th Victim Compensation Fund of 2001, 67 Fed. Reg. 11,233, 11,244 (Mar. 13, 2002) (final rule).

224. FEINBERG, *supra* note 219, at 10.

225. See *id.* at 65–66 (noting that procedures were created to facilitate coordination with various government and private organizations).

226. 49 U.S.C. § 40101 note (Air Transportation Safety and System Stabilization Act § 405(b)(4)(A)).

protect the fund, the special master or his designated hearing officers were repeatedly put in the position of having to defend the fund against potentially fraudulent claims.²²⁷ On a “significant number of occasions, victims and decision-makers [were] in an adversarial posture.”²²⁸

The first objective of this compensation program was to capture a very substantial share of the potential petitioners and get them to file in the Fund rather than in civil court.²²⁹ After these claims were filed with the Fund, the Fund’s objectives would then be to compensate the eligible parties generously, promptly, and fairly. Special Master Feinberg believed that after the September 11th Fund had expired, “everybody will agree it was a successful program.”²³⁰ It does appear that the compensation fund met its first objective very well. Ninety-seven percent of those eligible to file claims in connection with the September 11th attacks filed with the Fund.²³¹ Only ninety-six individual civil claims were filed by persons who selected that option instead of participation in the Fund.²³²

The September 11th Fund awarded compensation for 5,560 claims.²³³ The average award involving the death of the claimant was \$2,082,035, and the average award in an injury case was \$392,968.²³⁴ All but one of the ninety-six civil cases involving the September 11th attacks have now settled, for an average of approximately \$5.3 million per claim.²³⁵ The

227. Stephan Landsman, *A Chance to be Heard: Thoughts About Schedules, Caps, and Collateral Source Deductions in the September 11th Victim Compensation Fund*, 53 DEPAUL L. REV. 393, 403 (2003).

228. *Id.*

229. One author has noted that Special Master Feinberg “made urging victims to join the Fund one of his top priorities.” Berkowitz, *supra* note 221, at 27.

230. Kenneth R. Feinberg, Speech, *Negotiating the September 11 Victim Compensation Fund of 2001: Mass Tort Resolution Without Litigation*, 19 WASH. U. J.L. & POL’Y 21, 27–28 (2005). Special Master Feinberg continued:

The recipe for success was pretty clear: make very generous payments; outreach to the families; keep going after them and corral them; let them know that there are no tricks, and that nothing is hidden here. This is a transparent attempt by the American people to help. Offer due process considerations. Give everybody the opportunity to be heard. Make yourself available. Reach out to these people. It worked.

Id. at 27.

231. Hadfield, *supra* note 211, at 650.

232. *In re September 11 Litigation*, 600 F. Supp. 2d 549, 552 (S.D.N.Y. 2009)

233. FEINBERG, *supra* note 219, at 98–99. The fund received a total of 7,403 claims. *Id.* at 109.

234. *Id.* at 110.

235. Mark Hamblett, *9/11 Mediator Wraps Up Work; Only 3 Cases Left Unsettled*, N.Y.L.J., Mar. 6, 2009, at 1; Colin Moynihan, *Timetable Is Set for the Only Civil Trial in a 9/11 Death*, N.Y. TIMES, Oct. 21, 2010, at A32. The court-approved mediator for the civil cases reported to the court that settlements in the first ninety-three cases totaled approximately

court-approved mediator for the September 11th civil actions concluded that it was impossible to completely answer the question of whether similarly situated claimants did better in the September 11th Fund or by filing a civil suit.²³⁶

Many commentators have concluded that the September 11th Fund largely succeeded in providing compensation that was generous, prompt, and fair to the petitioners,²³⁷ as well as providing vital assistance to the airline industry at a time of exceptional distress.²³⁸ Other commentators have been critical of the September 11th Fund on a number of grounds, including the procedural fairness of the decisionmaking process, the arbitrary principles involved in determining individual awards, and the excessive discretion given to the special master with little accountability or oversight.²³⁹ In this Author's view the September 11th program was very largely successful, and it was so because Special Master Feinberg used his

\$500 million, although the specific amount of each settlement was confidential. Report of the Mediator on the Mediation and Settlement Efforts of the Parties in the Cases Previously Docketed Under 21 MC 97 at 13, *In re September 11 Litigation*, No. 21 MC 101 (AKH) (S.D.N.Y. Mar. 3, 2009) [hereinafter Report of the Mediator].

236. One reason why it was difficult to compare the amounts of the awards from the September 11th Fund and from the civil cases was that awards in the civil cases were generally subject to payment of substantial attorneys' fees and costs, while the September 11th fund case awards generally did not involve substantial attorneys' fees and costs. Report of the Mediator, *supra* note 235, at 14–15. Moreover, as the mediator noted, compensation in the civil cases was generally provided a substantial number of years after the September 11th Fund moneys were distributed, and the civil claimants had to bear the toll of prolonged and uncertain litigation as well as the delay in achieving some closure and financial security. *Id.* at 15. The mediator added that the “families of decedents with very high incomes probably achieved settlements that would have been unlikely achievable through the Fund because of the rules governing the Fund, including deductions for collateral sources of recovery such as life insurance policies.” *Id.*

237. James C. Harris, *Why the September 11th Victim Compensation Fund Proves the Case for a New Zealand-Style Comprehensive Social Insurance Plan in the United States*, 100 NW. U. L. REV. 1367, 1372 (2006) (comparing the Victim Compensation Fund to the New Zealand Plan and noting that both plans fairly compensate victims with minimal bureaucratic delay); Robert L. Rabin, *September 11 Through the Prism of Victim Compensation*, 106 COLUM. L. REV. 464, 478 (2006) (reviewing KENNETH R. FEINBERG, WHAT IS LIFE WORTH?: THE UNPRECEDENTED EFFORT TO COMPENSATE THE VICTIMS OF 9/11 (2005)) (“In fact, the resultant mix of presumptive scheduling tempered by personal empathy and pecuniary adjustments at the margin was the touchstone to the success of the program.”); Joe Wientge, Comment, *Foreseeable Change: The Need for Modification of the Foreseeability Standard in Cases Resulting From Terrorist Acts After September 11th*, 74 UMKC L. REV. 165, 195 (2005) (noting that the Fund “by most accounts awards a very just sum to participants”).

238. Ackerman, *supra* note 211, at 159–60; Hadfield, *supra* note 211, at 649.

239. Matthew Diller, *Tort and Social Welfare Principles in the Victim Compensation Fund*, 53 DEPAUL L. REV. 719, 725–26, 753–60 (2003); see also Ackerman, *supra* note 211, at 138–39 (discussing the funds two major shortcomings).

almost complete and unreviewable discretion to find a good balance between presumptive damages tables and personalized meetings with petitioners advocating for higher amounts of compensation. It was a unique inquisitorial procedure with a friendly face and a largely transparent decisionmaking process, resulting in relatively generous compensation awards.²⁴⁰

E. The Countermeasures Injury Compensation Program

In 2005, the Bush Administration became extremely concerned about a potential H1N1 avian flu pandemic as well as potential bioterrorism threats from anthrax and other toxins.²⁴¹ In order to encourage industry to participate in creating countermeasures to such threats, including making new vaccines, the Administration proposed a bill to provide industry with very sweeping liability protection. The bill also contained a compensation program for persons injured by the countermeasure that was so limited and restricted that Senators Ted Kennedy, Tom Harkin, and Christopher Dodd memorably noted, “Without a real compensation program, the liability protection in the . . . bill provides a Christmas present to the drug industry and a bag of coal to everyday Americans.”²⁴²

The Public Readiness and Emergency Preparedness Act of 2005,²⁴³ which contained the Countermeasures Injury Compensation Program, was passed on December 30, 2005, after Majority Leader Bill Frist attached the

240. More recently, Special Master Kenneth Feinberg was asked by President Barack Obama to administer the \$20 billion compensation program funded by British Petroleum in connection with the Gulf oil spill in 2010. Sheryl Gay Stolberg, *Administering the Fund, a Master Mediator*, N.Y. TIMES, June 17, 2010, at A18. Special Master Feinberg was even asked to administer a multimillion dollar compensation fund, created from funds donated to Virginia Tech that were dispersed to persons injured in a horrendous shooting incident on campus in 2007. Ian Urbina, *Sept. 11 Compensation Chief to Oversee Virginia Tech Payouts*, N.Y. TIMES, July 6, 2007, at A10. The September 11th program’s success sprang from giving Special Master Feinberg virtually total and unreviewable discretion in designing the compensation program and then in adjudicating the awards that were made in the program. So, as we look to the future, is the best answer we can come up with for a successful compensation program in a mass disaster situation to ask Kenneth Feinberg to take care of it, and get out of his way?

241. See HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA (2005) (addressing the threat of pandemic influenza); SARAH A. LISTER, CONG. RESEARCH SERV., RL 33145, PANDEMIC INFLUENZA: DOMESTIC PREPAREDNESS EFFORTS 32 (2005) (discussing the use of influenza as a bioterrorist weapon).

242. *Pandemic Funding, Liability Shield Clear Congress*, CTR. FOR INFECTIOUS DISEASE RES. & POL’Y (Dec. 28, 2005) (quoting Sen. Edward Kennedy) <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/dec2805liability.html>.

243. Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. §§ 247d-6d to -6e (2006)).

Countermeasures bill to a “must pass” military authorization bill.²⁴⁴ Under this Act, the Secretary of HHS is authorized to declare a public health emergency with respect to a naturally-occurring pandemic, a bioterrorism threat, or any other actual or potential public health emergency.²⁴⁵ To date, the Secretary has declared eight such public health emergencies, and has issued six subsequent amendments to these declarations.²⁴⁶

Once the Secretary declares a public health emergency, all parties who participate in the manufacture, testing, development, or distribution of the specified countermeasures are protected by the liability provisions of the Act.²⁴⁷ The Act requires that any person who believes that he or she may have been seriously injured by one of the covered countermeasures must first bring a claim for compensation in the Countermeasures Injury Compensation Program before bringing a civil suit for damages.²⁴⁸

Unfortunately, HHS refused to adopt procedural rules to decide cases brought under the Countermeasures Injury Compensation Program for almost five years after the law was passed. It was only in October of 2010 that HHS issued an Interim Final Rule authorizing the administrative implementations of the compensation program.²⁴⁹ HHS had previously announced that it would not process the claims it has already received involving adverse reactions to the 2009–2010 H1N1 swine flu vaccine or the other covered countermeasures until the agency issued rules for

244. See 151 CONG. REC. 30,726 (2005) (statement of Sen. Hatch); Sheryl Gay Stolberg, *Legal Shield for Vaccine Makers Is Inserted Into Military Bill*, N.Y. TIMES, Dec. 20, 2005, at A26.

245. 42 U.S.C. § 247d-6d(b)(1) (2006).

246. The Secretary of HHS has issued emergency declarations regarding: (1) Pandemic Influenza Countermeasures, on February 1, 2007; (2) Anthrax Countermeasures, on October 6, 2008; (3) Acute Radiation Syndrome Countermeasures, on October 17, 2008; (4) Smallpox Countermeasures, on October 17, 2008; (5) Pandemic Antiviral Countermeasures, on October 17, 2008; (6) Botulism Countermeasures, on October 17, 2008; (7) Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices and Respiratory Support Devices Countermeasures, on December 22, 2008; and (8) the Pandemic Antiviral Peramivir Countermeasure, on October 22, 2009. *Covered Countermeasures*, HEALTH RES. & SERVS. ADMIN., <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/declarations.html> (last visited Sept. 24, 2011) (listing *Federal Register* notices of emergency declarations). The Secretary has amended the Pandemic Influenza Declaration five times and the Pandemic Antiviral Peramivir Countermeasure Declaration once. *Id.*

247. 42 U.S.C. § 247d-6d(a)(1), (b)(1).

248. *Id.* § 247d-6e(d)(1).

249. Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. 63,656 (Oct. 15, 2010) (to be codified at 42 C.F.R. pt. 110).

adjudicating these cases.²⁵⁰ HHS disclosed, in response to a Freedom of Information Act request filed by this Author, that 230 claims had been filed involving the H1N1 swine flu vaccine, and that a few additional claims had been filed involving other countermeasures.²⁵¹

In this program, petitioners can bring a claim for compensation in one of two ways. First, petitioners can meet their burden of showing that there was a preponderance of evidence establishing that the specified countermeasure probably caused the injury.²⁵² In the alternative, if and when HHS publishes a Table of injuries with respect to any of the countermeasures, petitioners will then be entitled to a presumption that the countermeasure caused any injury listed on the Table, if it occurred within the time frame specified by the Table.²⁵³

The legislation for this program clearly intended nonadversarial processing of claims for compensation, with HHS officials making decisions after conducting nonpublic investigations.²⁵⁴ Judicial review is expressly precluded.²⁵⁵ The statute of limitations requires the claim to be filed within one year of the administration of the countermeasure that caused the injury,²⁵⁶ rather than one year from the onset of the first manifestation of the injury. Neither attorneys' fees nor costs are recoverable.²⁵⁷ The types of compensation available are very similar to those available through the Smallpox Compensation Program, with no compensation allowed for pain and suffering, and only partial, prorated amounts available for lost income,

250. U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH RES. & SERVS. ADMIN., COUNTERMEASURES INJURY COMPENSATION PROGRAM: PROGRAM UPDATE 7–8 (2010), <http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/nvac2010hrsa2-4v2.ppt#7>.

251. HHS indicated that as of July 12, 2010, it had received 230 requests for benefits regarding the H1N1 swine flu vaccine, 3 requests regarding the anthrax vaccine, and 1 request each with respect to the smallpox vaccine, the Japanese encephalitis vaccine, Relenza (zanamivir), and Tamiflu (oseltamivir). Letter from Thomas Flavin, Freedom of Info. Officer, Dep't of Health & Human Servs., to Peter H. Meyers, Professor, The George Wash. Univ. Law Sch. (July 21, 2010) (on file with Author).

252. 42 U.S.C. §§ 239a(c)(2), 247d-6e(b)(4). There is language in the Act indicating that petitioners must satisfy their burden of proof by introducing “compelling, reliable, valid, medical and scientific evidence.” *Id.* § 247d-6e(b)(4). This language does not appear to change the preponderant evidence requirement of the Act.

253. *Id.* § 247d-6e(b)(5)(A).

254. Cf. *id.* § 247d-6e(b)(4) (giving the Secretary of HHS broad authority to promulgate regulations).

255. *Id.* § 247d-6e(b)(5)(C).

256. *Id.* § 239a(d).

257. *Id.* § 247d-6e(b)(2); *Countermeasures Injury Compensation Program, How to File and Deadline for Filing*, HEALTH RES. & SERVS. ADMIN., <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/howtofile.html> (last visited Sept. 24, 2011).

as well as other applicable caps and exclusions.²⁵⁸ The Act allows all persons who have first exhausted their remedies in the compensation program to then file a suit for civil damages against a manufacturer or other provider covered by the Act. The Act specifies, however, that liability can only be found if the covered person was guilty of “willful misconduct.”²⁵⁹

The Act has been subjected to substantial criticism for the sweeping protections it affords industry and the restrictive provisions of the compensation program.²⁶⁰ However, these concerns did not appear to be a consequential factor during the H1N1 swine flu pandemic in 2009–2010. When supplies of the vaccine became widely available in December 2009, most Americans did not seek the vaccine for themselves or their families. *The New England Journal of Medicine* published a comprehensive evaluation of why this occurred.²⁶¹ The two principal reasons were safety concerns about the vaccine, including possible side effects, and the lack of concern about getting a serious case of swine flu if unvaccinated.²⁶² Other reasons were

258. 42 U.S.C. § 247d-6e(b)(2); *see also id.* §§ 239c–e. One area in which the Countermeasures Compensation Program appears to be more generous than the Smallpox Compensation Program is that the death benefit that a survivor can receive in the Countermeasures Compensation Program is not reduced depending on the amount awarded for lost income. *Id.* § 247d-6e(b)(2) (excluding the death benefit reduction provision of 42 U.S.C. § 239e(a)(2)(B)).

259. *Id.* § 247d-6d(d)(1).

260. *See, e.g.*, George W. Conk, *Will the Post 9/11 World be a Post-Tort World?*, 112 PENN ST. L. REV. 175, 227–232 (2007) (criticizing the various provisions of the Act); Lawrence O. Gostin & Benjamin E. Berkman, *Pandemic Influenza: Ethics, Law, and the Public’s Health*, 59 ADMIN. L. REV. 121, 135 (2007). A report issued by Public Citizen commented that:

Frist gave the companies immunity, but then went still further and stripped victims of meaningful recourse. In this regard, the bill was a drastic departure from precedent, shielding corporations from legal and financial accountability, but failing to replace them with a government surrogate or establish a guaranteed source of funds to cover losses. The recipients of pandemic products, their families, and society at large would be forced to shoulder the consequences of industry’s gross negligence, recklessness, deceptive claims, and failures to warn, among other egregious acts.

PUBLIC CITIZEN, WILLFUL MISCONDUCT: HOW BILL FRIST AND THE DRUG LOBBY COVERTLY BAGGED A LIABILITY SHIELD 19 (2006). Some have argued that the broad liability protections in the Act are desirable. *See, e.g.*, Paul Taylor, *We’re All in This Together: Extending Sovereign Immunity to Encourage Private Parties to Reduce Public Risk*, 75 U. CIN. L. REV. 1595, 1646–47 (2007).

261. Gillian K. SteelFisher, Robert J. Blendon, Mark M. Bekheit & Keri Lubell, *The Public’s Response to the 2009 H1N1 Influenza Pandemic*, 362 NEW ENG. J. MED. e65(1) (2010). This study was based upon an evaluation of twenty national public opinion polls. *Id.* at e65(1). By mid-January of 2010, 40% percent of polled parents had had their children vaccinated, and 21% of polled adults had received the vaccine. *Id.* at e65(5).

262. *Id.* at e65(3) to e65(4).

also given for not vaccinating, but concern about the lack of a meaningful compensation program was never raised in the public debate about the H1N1 program.²⁶³

This is in marked contrast to the earlier smallpox vaccination program, where the lack of a meaningful compensation program for injured people was a major cause of its failure. The next section of this Article will explore possible reasons for this different result, and compare this compensation program with the other compensation programs discussed.

III. COMPARATIVE EVALUATION OF THE VACCINE COMPENSATION PROGRAM AND OTHER RECENT COMPENSATION PROGRAMS

A comparative analysis and evaluation of the Vaccine Injury Compensation Program with other recent federal compensation programs reveals several important lessons.

A. The Adequacy of a Compensation Program Is Sometimes Crucial and Sometimes Irrelevant

The perceived adequacy or inadequacy of the compensation program regime can be essential to the viability of a mass vaccination or other governmental health program. One of the principle reasons that the Smallpox Vaccination Program for first responders collapsed was because of the inadequate safety net for those vaccinated and for those with whom they came in contact, including patients and their own family members. Doctor groups, nurses associations, hospitals, and even state health agencies were urging nonparticipation in the Smallpox Program, in part because of the inadequate injury compensation plan in an otherwise questionable program. Less than ten percent of the promised 500,000 first responders ever volunteered to receive the vaccine and become part of the program. The program was an abysmal failure, and the lack of an adequate compensation program played an important part in that result.

The history of the Smallpox Program has important lessons for the Vaccine Injury Compensation Program and for other potential government health or bioterrorism programs that Congress may consider adopting in the future. The Vaccine Compensation Program must be sure to maintain the confidence of the American people as a meaningful compensation program, and future programs must give careful consideration to

263. *Id.* at e65(4). Other significant reasons that people gave for not getting the vaccine included distrust that public health officials would provide correct information about vaccine safety, dislike of injections, a recommendation from a healthcare provider not to be vaccinated, and the expense of the vaccine. *Id.*

compensation provisions and procedures to ensure that they are adequate, and that they will be perceived to be adequate, by the effected groups.

The September 11th Compensation Program is a good example of how a user-friendly compensation program is essential to ensuring the success of the compensation plan. All persons injured in the September 11th attacks, or surviving family members, were required to make an irreversible decision up front about whether to file a civil action for damages, or file a petition in the compensation program and accept the damages awarded by the special master, with no chance for any review of the special master's decision. The fact that virtually everyone (97%) went into the compensation program, as opposed to filing a civil action, made the program a success in terms of seeking nearly universal participation. This could only have happened because the special master adopted presumptive compensation amounts with the opportunity for petitioners to advocate in person for upward adjustments in appropriate cases, creating both reasonable expectations of the damages that likely would be awarded and the flexibility to modify the damage amounts in special circumstances. This combination of an inquisitorial procedure with a friendly face, the opportunity for petitioners to participate in the compensation determination, and the relatively generous awards resulted in the success of this program.

There has also been one situation where the adequacy or inadequacy of a compensation program appears to have been irrelevant to the operation of the vaccination program. During the H1N1 swine flu pandemic in 2009–2010, the absence of a meaningful, operating compensation program was not a consequential factor in whether people decided to get the swine flu vaccine for themselves or their families. Why did the lack of a meaningful compensation program play an important role in the failure of the smallpox vaccination program, but the lack of a meaningful, operating compensation program turned out to be irrelevant to the H1N1 swine flu vaccination program?

There appear to be several reasons for this anomalous result. First, the lack of a meaningful smallpox compensation program was a large concern for doctors, nurses, and other first responders because they knew of the dangerous potential of the smallpox vaccine. However, the lack of a meaningful compensation program was not a substantial concern for the general public with respect to the swine flu vaccine because the issue for most people was whether to get the vaccination for an illness that they did not perceive as a particularly dangerous threat. People were thus not particularly concerned about the adequacy of the compensation program for a vaccine-related injury.

Second, there was a substantial time lag between the swine flu vaccination program in 2009–2010 and the Countermeasures Compensation Program, which was passed by Congress in 2005. This four-year gap meant that the details of the compensation program were remote and obscure when the government began the swine flu program. This is in sharp contrast to the Smallpox Compensation Program, where the inadequacies of the program were immediately apparent and were a large concern to the first responders who were being asked to take the smallpox vaccination.

Moreover, the target audiences for the smallpox and swine flu vaccine programs were very different. The smallpox vaccinations were intended for doctors, nurses, and other first responders, who were very sophisticated about the potential risks of the vaccine and therefore very sensitive to the need for an adequate compensation program to protect themselves, their families, and their patients. The focus of the swine flu vaccinations was the general public, and most people were not overly concerned about getting a serious case of the swine flu, so they did not focus on the adequacy of the compensation program.

It could be argued, based upon the swine flu example, that the details of the Vaccine Injury Compensation Program, and even whether the program is operational at all, are not important to the general public, and thus the success of vaccine immunization in the United States is not dependent on a petitioner-friendly injury compensation plan. However, this argument is risky at best. Vaccinations remain controversial for many Americans, including the parents of young children, and any action that undermines the public's confidence that the Vaccine Injury Compensation Program offers a safety net to those injured by the vaccines could substantially impair the continued success of the immunization program in this country.²⁶⁴

B. Inquisitorial/Adversarial Models of Adjudication

All of the compensation programs discussed in this Article, with the exception of the Vaccine Program, were based upon a nonadversarial, inquisitional model, in which the official who decides the case is primarily responsible for gathering the necessary evidence. In all of these programs,

264. Whenever a childhood vaccination is given in this country, the Vaccine Act requires that the recipient receive a statement from the healthcare provider that includes information from the CDC on possible adverse reactions to the vaccination and about the Vaccine Injury Compensation Program in case of a serious adverse event. 42 U.S.C. § 300aa-26. A public loss of faith in this compensation program risks lower immunization rates and undercuts the government's interest in encouraging parents to vaccinate their children and themselves.

except for the September 11th program, the final decision was made after a proceeding in which the person seeking compensation had no right to meaningful, active participation in the proceeding and no right to notice and a hearing on contested issues. The September 11th program's essentially inquisitional procedure was made open and consumer-friendly in a number of ways. Only the Vaccine Compensation Program was created with a blend of inquisitorial and adversarial features in which counsel for the parties play important roles in conducting the litigation, which usually involves contested evidentiary hearings focusing on the testimony of expert witnesses.

Why should these compensation programs have such different procedures for resolving claims? It may be that the legal and medical questions that the special masters have to decide in vaccine cases are more complex and thus require a more complex procedure than the eligibility issues presented in these other compensation programs. The task in those other programs is often more clerical: that of determining whether the submitted documentation supports eligibility in the program. There is certainly an important screening role to determine if the applicant does meet the criteria that Congress established, but the full-blown and expensive protections of a formal trial are generally not going to be necessary to resolve these cases, except perhaps in exceptional situations. The inquisitional model might work well in resolving the relatively simple question of whether a Vaccine Table injury has been established, but the much more complex causation-in-fact cases that now predominate in the vaccine compensation program benefit from using adversarial procedures, including opposing counsels' ability to bring in leading experts from numerous medical disciplines to testify in court. The adversarial model approach, in which petitioners get to actively participate in a hearing that is the basis for the resolution of the case, is also likely to appear fairer to the petitioners than a decision in which they did not participate that is issued after what will be perceived as a secret review of the case file.

One important reason for the success of the September 11th program was that the special master recognized that within the inquisitional structure created to decide cases, it was desirable to provide the opportunity for petitioners to advocate face-to-face with the decisionmaker, and thus to feel they were heard and had the opportunity to participate in the proceeding. It is far different, and far less satisfying to a petitioner, to merely file a request for compensation with supporting documentation and then wait for the decision.²⁶⁵ There are, of course, transactional costs of the

265. All of the compensation programs allow attorneys to assist the persons petitioning for compensation, but only the Vaccine Act and the Radiation Exposure Compensation

petitioners' greater involvement in the proceeding, including a potentially substantial additional commitment of time, possible financial costs, as well as the wear and tear of being involved in litigation. Despite these costs, petitioners generally seek and benefit from active participation in the proceeding.

C. Industry Protection/Altruism

Most of the compensation programs discussed in this Article were adopted primarily to protect industries that Congress considered too big or important to fail. This is certainly true for the Vaccine Injury Compensation Program, where Congress was responding principally to the need to prevent vaccine manufacturers from leaving the United States' market because of concerns over tort liability. Similarly, the principal purpose behind the Smallpox Compensation Program was to make the vaccine manufacturers exempt from any legal liability, with the federal government taking over the manufacturers' liability under the Federal Tort Claims Act.²⁶⁶ The September 11th Compensation Fund was passed primarily to protect the viability of the airline industry in a moment of severe crisis. Most recently, the Countermeasures Injury Compensation Program was adopted in 2005, primarily to shield vaccine manufacturers and other industries with liability protection and to encourage them to participate in governmental programs responding to major health threats.

The two exceptions are the Radiation Compensation Program and the Japanese-American internment compensation program, both of which appeared to be adopted for altruistic reasons to bring a measure of assistance and closure to the affected groups. Neither statute appeared motivated by a desire to protect any industry or commercial interests. When these two compensation programs were adopted in 1988 and 1990, there did not seem to be concerns about any industry liability problems.²⁶⁷

Program have provisions relating to attorneys' fees. The Vaccine Act provides for the payment of attorneys' fees and costs separate from the compensation that the petitioners receive, and authorizes fees even if the petitioner is unsuccessful so long as the case was not frivolous and was brought in good faith. 42 U.S.C. § 300aa-15(e). RECA authorizes the attorney to charge up to 2% or up to 10% of the award received, depending of the type of case. *See id.* § 2210 note (Radiation Exposure Compensation § 9(b)); 28 C.F.R. § 79.74 (2010).

266. *See* 28 U.S.C. § 1346(b) (2006) (stating liability provisions under the Federal Tort Claims Act); 42 U.S.C. § 239–239h (listing liability provisions for Smallpox Compensation Program).

267. Congress had immunized nuclear weapons contractors from suits for damages in 1985. *See* HENRY COHEN, CONG. RESEARCH SERV., 95-717 A, FEDERAL TORT CLAIMS ACT: CURRENT LEGISLATION AND JUDICIAL ISSUES 13–15 (2001). The federal government,

Instead, these compensation programs “fit with the national penchant for righting old wrongs, which seemed to pervade Washington during this period.”²⁶⁸

D. Types and Amounts of Compensation Awarded

The nature of the compensation awarded, and the monetary and nonmonetary components of the award, vary substantially among the different compensation programs. In cases where the petitioner has died, the Vaccine Program, as well as the Smallpox Compensation Program and the Countermeasures Program, award a statutorily determined amount of \$250,000 to the family.²⁶⁹ No specific death benefit was provided in the September 11th Fund legislation; the average amount awarded in that program by the special master in a death case was \$2,082,035.²⁷⁰ In both the Japanese-American internment program and the Radiation Program, the family was eligible to receive the full amount of compensation that would have been awarded to the deceased.²⁷¹

Two of the compensation programs, the Radiation Program and the Japanese-American internment compensation program, provided “compensation” consisting of an official government apology and a limited monetary award. In the Radiation Program, qualified individuals received between \$50,000 and \$100,000; in the Japanese-American internment compensation program, the monetary award was fixed at \$20,000. The partial monetary awards in these two programs served very different purposes. The \$20,000 award in the Japanese-American compensation internment program represented a meaningful, non-*de minimis* payment reinforcing the seriousness of the apology, which might have seemed hollow if it was only words, unaccompanied by a respectful gesture of monetary payment. Acceptance of the compensation and the apology allowed many Japanese-Americans to feel some measure of closure over their internment. In contrast, the partial monetary payments made in the Radiation Program were intended to provide some funds to pay for medical care or related services for sick or injured individuals. Acceptance of these limited payments proved especially problematic for many persons with serious medical conditions, such as former atomic workers who had developed

and not private companies, had been responsible for the Japanese-American internment process.

268. TITUS, *supra* note 163, at 153.

269. See 42 U.S.C. §§ 239e(a), 3796(a); *id.* § 247d-6e(b)(2); *id.* § 300aa-15(a)(2).

270. FEINBERG, *supra* note 219, at 116.

271. 50 U.S.C. app. § 1989b-4(a)(8) (2006); 42 U.S.C. § 2210 note (Radiation Exposure Compensation § 6(c)(4)).

cancer, where the provided compensation did not come close to covering their medical needs.

The Vaccine Act's mandate in injury cases was to provide complete, not partial, compensation for present and future medical needs, including all necessary and appropriate future therapeutic and related care, with no caps or specific limitations, plus additional money for pain and suffering (capped at \$250,000), and lost income (with certain limitations). Both the Smallpox Program and the Countermeasures Program have substantial limitations and caps on the compensation awarded that make them much less petitioner-friendly programs than the Vaccine Compensation Program.²⁷²

E. The Role of Judicial Review

The three most recent compensation programs—the Smallpox Program, the September 11th Compensation Fund, and the Countermeasures Program—do not allow judicial review of final decisions involving eligibility for compensation. The other three compensation programs do provide for judicial review, and the availability of judicial review has played a meaningful role in these programs.

There have been many important decisions from the U.S. Court of Appeals for the Federal Circuit that have defined the parameters of the Vaccine Act, and instructed the special masters on what criteria to apply in deciding cases, as was discussed in detail above. The Japanese-American internment compensation program also allowed judicial review, and several appeals were filed in court from denials of compensation. Most of these cases focused on the requirement in the Act that the individual was either forced to enter a camp or was “otherwise deprived of liberty” by governmental action during that time period.²⁷³ The court decisions played an important role in determining when an individual was “deprived of liberty” within the meaning of the Act, and therefore entitled to compensation.²⁷⁴ The Radiation Exposure Compensation Program also

272. See *supra* notes 193–200, 255–258 and accompanying text.

273. 50 U.S.C. app. § 1989b-7(2)(B)(i).

274. There are eight reported appeals from denials of compensation in the Japanese-American internment compensation program. Three appeals concluded that compensation was appropriate because the petitioners had shown that they satisfied the eligibility criteria: *Ishida v. United States*, 59 F.3d 1224, 1234 (Fed. Cir. 1995) (holding that petitioner born to parents of Japanese ancestry during the internment period is entitled to redress); *Odow v. United States*, 51 Fed. Cl. 425, 433 (2001) (ruling that federal curfews and travel restrictions preventing petitioner from returning to her home and limiting how far she could travel were sufficient restrictions on her liberty to justify compensation); *Sato v. United States*, 33 Fed. Cl. 818, 822 (1995) (determining that children born after parents fled their home during the detention period, who were thereafter prohibited by law from returning home, were

authorized judicial review, and the Court of Appeals helped define a number of the important provisions of the Act.²⁷⁵ Judicial review has thus played an important role in the three compensation programs that authorized it. There have been a number of appellate decisions in all three programs that have defined key terms in these statutes, sometimes reversing the denials of eligibility for compensation, and providing oversight of agency decision making.

F. Future of the Compensation Program Model

There has been substantial scholarly debate on the desirability of using the compensation program model to provide redress in mass tort situations. Thirty years ago, Professor Richard J. Pierce, Jr. argued that the tort system had failed to encourage safety or reduce accident costs, and he proposed the creation of a large new federal compensation program that would be responsible for compensating victims of virtually all accidents or safety-related injuries in America.²⁷⁶ Other scholars have argued for the creation of specific compensation programs, such as a permanent federal compensation program for victims of domestic terrorist attacks.²⁷⁷ Others

sufficiently deprived of liberty to justify compensation). Five cases affirmed the denial of compensation: *Murakami v. United States*, 398 F.3d 1342, 1353 (Fed. Cir. 2005) (refusing to grant relief to a petitioner, born to parents of Japanese ancestry under the Act, based on the alleged constitutional harms suffered by his father); *Higashi v. United States*, 225 F.3d 1343, 1349 (Fed. Cir. 2000) (stating that petitioner born to parents of Japanese ancestry after restrictions on parents were rescinded not eligible for redress); *Kaneko v. United States*, 122 F.3d 1048, 1053–54 (Fed. Cir. 1997) (holding that petitioner of Japanese ancestry was not eligible for compensation where termination of his employment with a railroad was not due to government action); *Shibayama v. United States*, 55 Fed. Cl. 720, 745 (2002) (concluding that petitioner of Japanese ancestry who was not a citizen or permanent resident during the internment period is not eligible for redress under the Act); *Obadie v. United States*, 52 Fed. Cl. 432, 442 (2002) (holding that Americans of African ancestry do not have a right to seek reparations under the Act), *cert. denied*, 540 U.S. 876 (2003).

275. See, e.g., *Sharp v. United States*, 80 Fed. Cl. 422, 429 (Fed. Cl. 2008) (holding that RECA payments and Department of Veterans Affairs benefits offset each other); *Hackwell v. United States*, No. 04-cv-00827-EWN, 2008 U.S. Dist. LEXIS 56641, at *23 (D. Colo. 2008) (stating that limitations on payment of attorneys' fees do not include expenses incurred in the litigation); *Howell v. Reno*, 939 F. Supp. 802, 807–09 (D. Colo. 1996) (ruling that RECA can constitutionally distinguish between cigarette smokers and nonsmokers in determining eligibility for compensation).

276. Richard J. Pierce, Jr., *Encouraging Safety: The Limits of Tort Law and Government Regulation*, 33 VAND. L. REV. 1281, 1320 (1980).

277. See Betsy J. Grey, *Homeland Security and Federal Relief: A Proposal for a Permanent Compensation System for Domestic Terrorist Victims*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 663, 749 (2006).

have argued that the compensation program model should be abandoned in favor of reform of the tort laws.²⁷⁸

The experience of the compensation programs adopted by Congress in recent years present a mixed picture of success and failure. The Smallpox Program for first responders failed in part because of its inadequate injury compensation plan. The Countermeasures Compensation Program was totally dysfunctional for almost five years, with no procedural rules in place to process cases. The September 11th program is generally agreed to have been a successful compensation program that provided compensation quickly, transparently, and with relative generosity. The Vaccine Compensation Program does some things well, but also continues to have serious problems.

IV. PROPOSALS TO FIX THE VACCINE COMPENSATION PROGRAM

The Vaccine Injury Compensation Program has succeeded very well in accomplishing many of its objectives, particularly in providing excellent liability protection for the pharmaceutical industry that makes the vaccines, as well as the doctors and other healthcare providers who administer them. The interests of federal health officials have also been largely satisfied, as there has been a generally constant supply of vaccines available to the public, and a large percentage of the American public receive the inoculations.

However, Congress's other objectives of ensuring that the Compensation Program works "quickly, easily, and with certainty and generosity"²⁷⁹ have not been satisfied. This Article proposes a number of changes that would allow the Vaccine Act to much more effectively fulfill these important goals.

A. Adopt a Legal Standard of Proof More Generous to Petitioners

The Vaccine Act currently requires petitioners to prove their cases by the "more likely than not" or "preponderance of the evidence" standard.²⁸⁰ There is substantial confusion and uncertainty in applying this standard today. Several recent Federal Circuit decisions, emphasizing Congress's compassionate intent in the statute, have held that "close calls regarding causation" should be resolved in favor of petitioners,²⁸¹ while other recent Federal Circuit cases have emphasized that traditional tort causation

278. See Conk, *supra* note 260, at 257.

279. H.R. REP. NO. 99-908, pt. 1, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344.

280. 42 U.S.C. § 300aa-13(a)(1) (2006).

281. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009); Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

standards should be strictly applied in off-Table cases.²⁸² This has created an unpredictable and confusing situation. Congress should act to clarify the burden of proof requirement central to the resolution of off-Table cases.

In this Author's view, the Vaccine Act should be amended to allow petitioners the benefit of a more explicitly relaxed standard of proof of causation, similar to the standard of proof adopted for petitioners in other recent American and international compensation laws, which give petitioners the "benefit of the doubt" in close cases.²⁸³ Several of the other recent federal compensation laws have adopted more relaxed standards of proof for petitioners. The Radiation Exposure Compensation Act provides that any "reasonable doubt with regard to whether a claim meets the requirements of this Act shall be resolved in favor of the claimant."²⁸⁴ The Japanese-American internment compensation law contained a "benefit of the doubt" provision that mandated compensation if there was "an approximate balance of positive and negative evidence" with respect to a claimant's eligibility.²⁸⁵ Similarly, the Department of Veterans Affairs statute provides that an injured veteran is entitled to the benefit of the doubt on whether the veteran is entitled to disability compensation in a close case.²⁸⁶ There are also a number of international compensation programs that have adopted a more lenient standard for petitioners to satisfy.²⁸⁷ This generous standard should be incorporated into the Vaccine

282. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322–23 (Fed. Cir. 2010); De Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008).

283. An excellent article advocating for a "benefit of the doubt" standard favoring petitioners in vaccine cases is Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426 (2007). Adopting this standard would increase the payments made from the vaccine fund, but the fund has had a substantial surplus that should not make this a problem. See U.S. DEP'T OF THE TREASURY, VACCINE INJURY COMPENSATION TRUST FUND 75X8175 at 5 (2011), <ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfvri0811.pdf>.

284. 42 U.S.C. § 2210 note (Radiation Exposure Compensation § 6(b)(1)).

285. 50 U.S.C. app. § 1989b-4(a)(3) (2006).

286. 42 U.S.C. § 300aa-13(a)(1).

287. For example, the Claims Resolution Tribunal for Dormant Accounts in Switzerland, which provides compensation for victims whose assets were deposited in Swiss banks and then lost during the reign of the Nazis, are only required to show that it is "plausible" that they are entitled to compensation. The CRT Rules of Procedure, Article 17, as amended, provides that: "Each Claimant shall demonstrate that it is plausible in light of all the circumstances that he or she is entitled, in whole or in part, to the claimed Account." CLAIMS RESOLUTION TRIBUNAL, RULES GOVERNING THE CLAIMS RESOLUTION PROCESS (AS AMENDED) 10 (2000). Similarly, the United Nations Compensation Commission, established to pay compensation for injuries suffered as a result of Iraq's invasion and occupation of Kuwait, required that a claim be supported by "appropriate evidence sufficient to demonstrate the circumstances and amount of the claimed loss," with a "lesser degree" of documentary evidence necessary "for smaller claims." Decision Taken

Act. It is justified by both the compassionate intent of Congress in adopting the Vaccine Injury Compensation Program, and the uncertainty and unknowns in the vaccine-injury area that often make it very difficult to show a causal relationship between a vaccination and a subsequent adverse event.

B. Provide that All Provisions of the Vaccine Act Be Construed Liberally

As noted above, there are unresolved questions about the underlying philosophy of the Vaccine Act. The Act is sometimes described as a generous compensation statute that should be liberally construed in favor of compensating injured parties, but it has also been described as a statute waiving sovereign immunity that is to be strictly construed in favor of the government. There is language in the Federal Circuit's decisions supporting both points of view.²⁸⁸ It would be desirable for Congress to resolve these inconsistent rulings. Congress should recognize that the compassionate intent behind the Act is best embodied in a generous application of its terms that will allow the Vaccine Compensation Program to operate with the "generosity" that Congress intended.²⁸⁹

C. Amend and Expand the Statute of Limitations

The current statute of limitations provision contained in the Vaccine Act²⁹⁰ requires a person to file a claim within three years of the first onset of the manifestation of an illness, or within two years after a death (and within four years of the first symptom that lead to the death). According to the Federal Circuit's *Brice* decision, if the petition is filed late, the court has no jurisdiction to consider it, and there can be no equitable tolling of the statute to permit excusable failures to meet the statutory deadlines.²⁹¹ Many petitioners have missed filing deadlines for reasonable and potentially excusable reasons, such as in *Brice*, where the pro se petitioners were facing

by the Governing Council of the United Nations Compensation Commission at the 27th Meeting, Sixth Session, held June 26, 1992, at 19, U.N. Doc. S/AC/.26/1992/10 (June 26, 1992).

288. *Compare Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–80 (Fed. Cir. 2009) (holding that causation standards are to be liberally construed in generous compensation law), *with Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322–23 (Fed. Cir. 2010) (declaring that traditional tort standards should be strictly applied in off-Table cases).

289. H.R. REP. NO. 99-908, pt. 1, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344.

290. 42 U.S.C. § 300aa-16(a)(2)–(3).

291. *Brice v. Sec'y of Health & Human Servs.*, 240 F.3d 1367, 1367–68 (Fed. Cir.), cert. denied 534 U.S. 1040 (2001).

delays in getting complete medical records to file along with the petition, while simultaneously trying to find an attorney to represent them.²⁹² The statute should be amended to extend the time for filing both injury and death cases. Three years is an unnecessarily short time limit to file a petition in the Vaccine Program. The HHS Advisory Committee on Childhood Vaccines recommended a six-year statute of limitations, and bills proposing the six-year period have been introduced in Congress.²⁹³ A modification to six years, or even ten years, would reflect the basic “generous” purpose of the Vaccine Act.²⁹⁴ In addition, equitable tolling should be allowed, as determined by the courts, on a case-by-case basis. Once a new statute of limitations has been adopted, the special masters should also have the option of reconsidering old cases dismissed for late filing that would have met the new statute of limitations deadline.

D. Fix Attorney Compensation Problems

The payment of attorneys’ fees and costs has generated considerable litigation in the Vaccine Program. The statute should be amended to pay appropriate market rates for these complex vaccine injury cases,²⁹⁵ and make both interim and final fee payment procedures quicker, less adversarial, and more predictable.²⁹⁶ The U.S. Court of Federal Claims currently has a dedicated and experienced, but small, bar of petitioners’ counsel, and it must support those attorneys with reasonable, promptly paid fees. This is also necessary to encourage other experienced attorneys to assist in these cases in the future. The switch to predominantly off-Table cases in the Program has also resulted in cases that are often much more complex, both medically and legally, requiring substantially greater time and work, and imposing higher expert witness fees and other costs that the court must pay promptly and fully.

292. *Id.* at 1369.

293. See, e.g., National Vaccine Injury Compensation Program Improvement Act of 2008, H.R. 6391, 110th Cong. § 7 (2008).

294. H.R. REP. NO. 99-908, pt. 1, at 3.

295. The Federal Circuit has held that attorneys’ fees are to be calculated using the rate of the forum where the case is pursued. *Avera v. Sec’y of Health & Human Servs.*, 515 F.3d 1343, 1348 (Fed. Cir. 2008).

296. *Avera* also held that the special masters could grant interim payments of attorneys’ fees and costs in appropriate circumstances. *Id.* at 1352. No effective process has yet been developed before the special masters to make interim fee payments quicker and more predictable. Unless the courts act to remedy this on an administrative level, the attorney fee section of the Vaccine Act, 42 U.S.C. § 300aa-15(e) (2006), could be amended to provide for the prompt payment of interim fees according to a formula provided by Congress.

E. Allow Parents to Sue for Their Own Injuries

As currently drafted, the Vaccine Act allows only the party directly injured by the vaccine to bring a claim for compensation under the Act.²⁹⁷ As a result of this limitation, the Vaccine Act provides no protection for manufacturers or doctors being sued by family members of vaccine-injured persons for injuries recognized by state law, such as loss of companionship and loss of consortium.²⁹⁸ The Vaccine Act should be amended to allow the parents of a minor child, or the spouse of an adult, to be named as an additional party to the case, in order to seek compensation for their own pain and suffering, lost income, and expenses incurred. Of course, if such a petitioner accepts the award in the vaccine case, the petitioner must forgo the possibility of collecting an award in a separate civil action.

F. Raise the Caps on Death Benefits and Pain and Suffering Benefits

Under the Vaccine Act, as originally enacted in 1986, the payment for a vaccine-related death is a one-time lump sum payment of \$250,000. Similarly, compensation for any pain and suffering that an injured petitioner may have experienced, and will likely experience in the future, is capped at \$250,000.²⁹⁹ Even assuming that \$250,000 was appropriate when the law was first adopted, \$250,000 in 1986 dollars is not the same as \$250,000 in 2010 dollars. Accounting only for inflation, \$250,000 in 1986 dollars is equivalent to over \$500,000 in 2011 dollars.³⁰⁰ The awards in death cases should be raised to this amount, not only to reflect the actual value of the award in 2011 dollars, but also to better reflect the value of a human life, and to reach a result more consistent with the awards made in

297. See 42 U.S.C. § 300aa-13(a)(1).

298. Several decisions have held that the Vaccine Act only applies to the person injured by the vaccination, and that family members are not precluded from bringing their own civil action for compensation for injuries such as loss of companionship and loss of consortium. *Moss v. Merck & Co.*, 381 F.3d 501, 505 (5th Cir. 2004); *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 5 (1st Cir. 1994); *McDonald v. Lederle Labs.*, 775 A.2d 528, 535 (N.J. Super. Ct. App. Div. 2001).

299. In fact, in this Author's experience, the statutory cap of \$250,000, as currently interpreted by the special masters, means that the total amount assigned to pain and suffering can virtually never be \$250,000, because any money allocated to future pain and suffering is reduced to present day value, but money allocated to past pain and suffering is not increased to present day value.

300. The U.S. Bureau of Labor Statistics Inflation Calculator indicates that \$250,000 in 1986 had the same buying power that \$516,754 has in 2011. See *CPI Inflation Calculator*, U.S. BUREAU OF LABOR STATISTICS, <http://data.bls.gov/cgi-bin/cpicalc.pl> (last visited Sept. 24, 2011). The Vaccine Compensation Program routinely uses Bureau of Labor Statistics calculations in computing final damage awards.

the September 11th program. Similarly, the cap for pain and suffering should also be raised to \$500,000, to reflect the value of the award in 2011 dollars, and to more accurately reflect the value of the pain and suffering that many people with seriously injuries suffer for their entire lives.

G. Allow Expenses for Guardianships and Conservatorships and Family Counseling

Petitioners are sometimes required to set up court-ordered guardianships and conservatorships in state court as part of a vaccine case settlement. The expenses in setting up these proceedings have been considered reimbursable expenses to the petitioner in some cases, but not in other cases in the Vaccine Program. It would be fair and appropriate to compensate petitioners for these expenses in all cases, because they are incurred only as a result of court-mandated procedures in the vaccine case. Expenses for family counseling services are generally not reimbursable to petitioners today. These services can be of critical importance to the injured person and their family members, and should also be reimbursable to petitioners. In addition to these suggestions for legislative action, there are important steps the Court of Federal Claims and the Government Accountability Office could take.

H. The Court of Federal Claims Should Undertake a Comprehensive Review of the Vaccine Injury Compensation Program

The U.S. Court of Federal Claims, perhaps under the leadership of the Chief Judge and the Chief Special Master, could convene meetings at which all the applicable stakeholders, including attorneys from petitioners' bar, the Department of Justice, the Department of HHS, the special masters, and advocates for vaccine-injured individuals could discuss the operation of the compensation program and seek some consensus on measures that could be taken to improve it. The court does facilitate dialogue among the participants through Process Committee meetings, brown bag lunches, conferences, and other mechanisms. However, these mechanisms have proven insufficient to address the serious ongoing systemic problems with the Vaccine Compensation Program.

I. The GAO Should Conduct Another Oversight Review of the Program

The U.S. Government Accountability Office has conducted a number of evaluations of the Vaccine Injury Compensation Program over the years, and it has documented a number of serious problems in the operation of the program, including delays in resolving cases, the overly adversarial nature of the cases, and problems with payment of attorneys' fees. The

GAO has a long history of reviewing this compensation program, but it has been more than a decade since the GAO conducted a comprehensive review. It would be desirable for the GAO to investigate and report on the current operations of, and problems with, the Vaccine Compensation Program, as discussed in this Article. The flaws in the current operation of the Vaccine Injury Compensation Program should be investigated and fixed.

CONCLUSION

The Vaccine Injury Compensation Program is no longer the quick, informal, and less adversarial program that Congress intended it to be—and that it was in its early years, when the program focused on cases involving the law's innovative Vaccine Injury Table. The Vaccine Program has changed substantially over the past two decades, with more complex, time-consuming, and controversial off-Table cases predominating the court's docket today and for the foreseeable future. In light of these changes and the lessons learned from the five other major compensation programs that Congress has passed in the years since the adoption of the Vaccine Act, this Article argues for a number of statutory changes, including a lowered burden of proof for petitioners, so that the Vaccine Act can operate in the manner that Congress intended and that petitioners deserve.

The Vaccine Act has succeeded in satisfying the interests of vaccine manufacturers, the interests of doctors and other healthcare providers, and the interests of the federal health agencies involved in the vaccine area. However, the Act has not succeeded in satisfying the interests of the petitioners. While the Vaccine Program does a number of things well, it must be substantially reformed to become much friendlier to petitioners if it is to fulfill the final key Congressional goal of insuring that the interests of those people who are injured by vaccines will receive compensation that is provided “quickly, easily, and with certainty and generosity.”³⁰¹

301. See H.R. REP. NO. 99-908, pt. 1, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6344.